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**NUCLEAR REGULATORY COMMISSION**

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Draft Regulatory Basis to Clarify the  
Requirements of Title 10 of the Code of  
Federal Regulations Part 21

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UNITED STATES OF AMERICA  
 NUCLEAR REGULATORY COMMISSION

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DISCUSSION ON REVISION ONE OF THE DRAFT REGULATORY BASIS  
 TO CLARIFY THE REQUIREMENTS OF TITLE 10 OF THE CODE OF  
 FEDERAL REGULATIONS PART 21

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PUBLIC MEETING

+ + + + +

TUESDAY

APRIL 28, 2015

+ + + + +

ROCKVILLE, MARYLAND

+ + + + +

The Meeting met at the ASLBP Hearing Room,  
 Two White Flint North, Rockville, Maryland, at 9:00 a.m.

PRESENT:

LISA CLARK, Facilitator

SABRINA ATACK, NMSS/FCSS

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SIDNEY BERNSEN \*

THOMAS BIAGI, Parker Hannifin\*

ALAN BLAMEY, Region 2 Division of Fuel Facility

Inspection\*

KEVIN BONSER, General Atomics \*

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ASHLEY THOMAS, NRC

ANDREA VALENTIN, NRC

\* present by telephone

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

(9:04 a.m.)

1  
2  
3 MS. CLARK: Morning, everybody. Can  
4 everybody hear me okay?

5 My name is Lisa Clark. And, operator,  
6 could you please begin our meeting?

7 OPERATOR: You are now live.

8 MS. CLARK: Thank you. My name is Lisa  
9 Clark and I'm a member of the facilitator corps here at  
10 the NRC, and it's my pleasure to facilitate our meeting  
11 this morning.

12 My role today will be to just cover  
13 logistics and to try to ensure that the meeting goes  
14 along as smoothly as possible.

15 I'd like to begin by just covering some  
16 basic logistics today. You will notice on the ledge  
17 here we have copies of the slides that you'll be showing  
18 today. We also have an attendance sheet that's  
19 circulating. Please be sure to sign that. And we also  
20 on the ledge have some meeting feedback forms and we  
21 would ask that you fill those out when we're done today.  
22 Your feedback is very important to us and helps us to  
23 continually improve our public meetings.

24 The purpose of today's meeting is to discuss the  
25 NRC's regulatory analysis of a potential rulemaking to

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1 revise Part 21. And before I get into that a little  
2 more, I have some more logistics to cover.

3 First of all, when you leave this hearing  
4 room, even if you're just walking to the restrooms, for  
5 example, on this floor, you will need to be escorted.  
6 We will have some staff members on hand. I don't know  
7 if they're here today. If you could stand up, please,  
8 in the back? So, if you need to leave at any time, just  
9 please tell one of those and they will take you where  
10 you need to go.

11 The restrooms are located -- if you go past  
12 the elevators, ladies' room is on the right, men's room  
13 is on the left.

14 We will have two breaks today. Fifteen  
15 minutes in the morning, 15 minutes in the afternoon, and  
16 we will also break an hour for lunch.

17 When you go downstairs to the first floor,  
18 you don't need an escort. Once you're down there, you  
19 can go to the cafeteria, go in and out of the building.  
20 We will send escorts down like 5, 10 minutes before the  
21 meeting resumes and they will bring you back upstairs.

22 In the meeting room only water is allowed.  
23 No other food or drinks in this room for the meeting  
24 today.

25 Our meeting is going to be divided into two

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1 separate sessions, morning and afternoon. In the  
2 morning session we're going to talk about the regulatory  
3 basis for the proposed rulemaking in the areas of  
4 evaluation and reporting and commercial grade  
5 dedication as they pertain to power reactors. In the  
6 afternoon we're going to cover regulatory basis for  
7 proposed rulemaking in the areas of evaluation and  
8 reporting and commercial grade dedication as they  
9 pertain to fuel cycle facilities.

10 This is a Category III meeting, meaning  
11 it's open to the public and provides an opportunity for  
12 comments and questions. Therefore, we will not be  
13 talking about any sensitive or proprietary information  
14 today.

15 Our agenda is going to cover a number of  
16 topics, and Jermaine is going to talk to you in more  
17 detail about our agenda today. They represent those  
18 areas of Part 21 for which the staff is considering  
19 rulemaking.

20 For each segment the staff will give a short  
21 presentation after which we will open up the meeting for  
22 public comments and questions.

23 We have a fairly tight schedule today.  
24 We're covering a lot of different topics, so I'm going  
25 to ask you to please try to make your comments brief so

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1 we can hear from as many participants as possible. And  
2 also, if you can please try to keep your questions and  
3 comments limited to the topic we're discussing at the  
4 time. We do have time set aside this afternoon for open  
5 discussion, so if you have comments or questions about  
6 matters we're not specifically covering, that would be  
7 the time for you to raise those particular matters.

8 As a reminder, we're not soliciting formal  
9 comments at this meeting, but we will shape the final  
10 regulatory basis based on the input that you provide  
11 during the public meeting today.

12 Our meeting today is being transcribed,  
13 therefore I ask that you please state your name and  
14 affiliation before stating any question or comment.  
15 Also, it's very important that we have only one person  
16 speak at time so that the transcription will be clear  
17 and it's easy for our person who's transcribing today  
18 to get a clear and accurate transcript.

19 We also have folks participating in the  
20 meeting today, as you probably heard this morning. For  
21 that reason I ask that when you make comments or  
22 questions, please use the microphone standing there so  
23 the people on the phone can hear you.

24 I'll tell you these microphones in this  
25 room are very sensitive, so you don't need to get up too

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1 close. In fact, if you get too close, the microphone,  
2 it's probably going to cut out on you. So please keep  
3 maybe 6, 12 inches away when you speak.

4 Let's see. And again, we have our public  
5 meeting forms. Once you fill them out, you can leave  
6 them with a staff member here or you can put them in the  
7 mail. Postage is free.

8 And I think that covers our logistics, so  
9 I'm now going to turn the meeting over to Jermaine.

10 MR. HEATH: All right. Good morning,  
11 everyone, and welcome to NRC Headquarters. My name is  
12 Jermaine Heath and I am the lead for the Part 21  
13 rulemaking effort here at the Agency.

14 So what I'll do, as I move through the  
15 meeting, for those on the bridge, is I'll try to call  
16 out the slides as I go through them to kind of help you  
17 keep up with where I am. So, let's go ahead and go  
18 through slide 2 and hit slide 3, and get right to the  
19 purpose.

20 Before I begin, I'd like to clarify -- I  
21 think we said before there was no food or beverage  
22 allowed. I did find out late-breaking that there is  
23 water allowed in here. So I have my bottle of water.  
24 I actually feel kind of bad because I have water and no  
25 one except for Victoria seems to have anything to drink.

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1 MS. HUCKABAY: Water.

2 MR. HEATH: I do apologize for that. So on  
3 a break or back from lunch if you want to bring some water  
4 in, that should be fine.

5 So, why are we here today? So, the purpose  
6 of today's rulemaking public meeting, we issued  
7 Revision 0 to the draft regulatory basis to clarify Part  
8 21 back in December of 2012. There's been a lot of  
9 legwork that staff has done since those few years back  
10 since the release of the reg basis and numerous public  
11 outreach efforts, internal work by the staff to try to  
12 understand how to deal with the compliance challenges  
13 associated with Part 21. So, last month, in March we  
14 released Revision 1 to the draft regulatory basis after  
15 all that work. So, the purpose of today's meeting is  
16 to discuss the findings of the staff and present our  
17 case, and specifically to show you all where we're  
18 proposing rule language as it relates to Part 21.

19 Slide 4, please. So, briefly I will go  
20 over the meeting agenda. As Lisa said, this morning is  
21 going to focus on the operating reactors piece, so we'll  
22 be going through the slide topics that you see here up  
23 on the slide.

24 Next slide, 5. There was one change. I  
25 sent this out yesterday. It's kind of late-breaking.

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1 There's a minor change I just want to bring to your  
2 attention, that we're going to have the open discussion  
3 period -- it was originally scheduled from 4:15 to 5:00  
4 for operating reactors. We've moved it up to  
5 immediately after lunch, that and the administrative  
6 changes. The administrative changes is a very small  
7 portion of what we're doing today. And then we're going  
8 to follow that up immediately and have open discussion  
9 pertaining to this morning's session, which is  
10 involving operating reactors. After that we'll have a  
11 break and then the remainder of the meeting will be  
12 reserved for fuel cycle facilities. That's a change  
13 from slide that you'll have.

14 Next slide, slide 6. The Part 21 Working  
15 Group has changed a bit since it was originally formed  
16 back in 2010. I'm leading the effort now. Again, my  
17 name is Jermaine Heath. I'm with NRO, Division of  
18 Construction Inspection and Operational Programs.  
19 With me I have Victoria Huckabay. She's my backup on  
20 this, so she's helped out tremendously with this effort.  
21 And also Paul Prescott. He's new to the working group,  
22 but he's not new to Part 21. So, many of you all are  
23 familiar with Paul.

24 So, as I was saying before, the purpose of  
25 the working group when it was assembled and to this day

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1 is to help to identify those areas of Part 21 that we  
2 feel need improvement. And at this phase of the  
3 rulemaking we're trying to develop the regulatory or  
4 technical basis for the rulemaking.

5 Next slide, slide 8. This slide is a  
6 repeat. We've used it frequently, but it's really  
7 good. I like this slide because it gives you a broad  
8 picture of the rulemaking timeline to kind of show you  
9 where we are in space. Up there in red you can see we're  
10 in the regulatory, the technical basis phase where we  
11 essentially provide our basis for moving forward with  
12 rulemaking. And that was the Revision 1 to the draft  
13 reg basis that we issued last March. That's where we  
14 are.

15 So, once that gets finalized, the next  
16 phase of that will move over into the proposed rule phase  
17 where we're actually begin drafting the rule language.  
18 And that will be followed by a comment period of 75 days  
19 in which we'll solicit feedback. But again, so we  
20 intend to finalize the regulatory basis here in the next  
21 couple of months and then we'll move over into the  
22 proposed rule phase once that's finished.

23 Next slide. I won't spend too much time  
24 here. This is just a history for those who may be  
25 unfamiliar with the Part 21 rulemaking effort. Back in

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1 2009 we drafted the memo which identified the need to  
2 clarify Part 21 based on the number of findings, the  
3 compliance challenges that the staff saw out in the  
4 industry when we've been doing our inspections of Part  
5 21 including commercial grade. So, in 2010 there were  
6 two OIG audits that identified several areas of Part 21.  
7 There were a number of recommendations, and a lot of  
8 those focused on clarifying Part 21. Then in 2011 the  
9 staff issued a SECY paper, and it's noted there on the  
10 slides notifying the Commission of our intent to develop  
11 the regulatory basis for Part 21. Then 2012 is when we  
12 issued the initial draft.

13 Next slide, slide 10. Since the issuance  
14 of the initial draft I think we've had a number of public  
15 outreach efforts. I think there's been six public  
16 meetings that we've had. We're trying to solicit input  
17 and gather feedback to try to understand how we can make  
18 Part 21 better and make it more clear and easier for not  
19 only our stakeholders, but for internal staff to cope  
20 with.

21 So, just moving forward, again we plan to  
22 issue a final regulatory basis following comments  
23 received from this meeting in June, and then we'll move  
24 over into the proposed rule phase, which we intend to  
25 shape up some time in 2016, following the schedule.

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1           Next slide, 11. So, the purpose of the  
2 Part 21 rulemaking, again to address those issues  
3 identified in the user memo from 2009, the SECY paper  
4 in 2011, the two OIG audits, and then the findings of  
5 the Part 21 Working Group.

6           So, the rulemaking intends to clarify Part  
7 21 through a combination of methods. So, the staff  
8 examined changes to the regulations. We also looked at  
9 NRC-generated guidance documents and also we're taking  
10 into consideration industry-drafted documents and  
11 their possible endorsement. The alternative is to do  
12 nothing, but I can go ahead and tell you now with all  
13 the areas that the staff identified none of our  
14 solutions involve doing nothing. So, there's a  
15 combination of both proposed rules and guidance to  
16 remedy the issues we have with Part 21. So today's  
17 meeting only focuses on those areas where we're  
18 proposing rule change, not those areas where we feel  
19 like guidance is the right way to go.

20           Next slide, 12. What I want to say here,  
21 and I'll move through this one quickly also, is that  
22 staff originally identified 25 areas of improvement.  
23 The 2010 working group identified 25 areas of  
24 improvement that were split amongst 3 different  
25 categories. We looked at Part 21 as evaluation and

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1 reporting part. Then there's the commercial grade  
2 dedication piece. And then the staff looked at  
3 administrative changes. We came up with 25 areas.  
4 They're mostly the same. They've kind of morphed and  
5 changed a little bit, but they're more or less the same  
6 25 areas that the original working group decided on.  
7 But we've fine-tuned and honed in, thrown an area out  
8 and brought an area in. So, but they're more or less  
9 the same.

10 Next slide, 13. So, an important part of  
11 this rulemaking effort, as I said before, is the  
12 regulatory guidance. There are a number of draft  
13 guidance documents that are currently in the works.  
14 They're listed here on your slides: Draft Guide 1291,  
15 1292 and Draft Guide 1305 that we're reviewing in  
16 concert with the rulemaking proposal.

17 Next slide, 14. So Draft Guide 1291 deals  
18 with the evaluation and reporting part of Part 21. The  
19 staff will be developing that guidance along with the  
20 rulemaking. There's currently industry guidance out  
21 there that also covers the evaluation reporting aspects  
22 of Part 21. That is NEI 14-09. That is the staff has  
23 it in its hands, is currently reviewing that for  
24 potential endorsement. It's very early on, but the  
25 staff is reviewing it.

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1                   Next slide, 15. Draft Guide 1292, the NRC  
2 is developing also, which covers the commercial grade  
3 dedication aspect of Part 21. There is industry  
4 guidance out there. EPRI Revision 1 to 5652, which  
5 covers the commercial grade dedication. The staff has  
6 it in its possession also as of, I think it was fall of  
7 last year. So that document is currently in review for  
8 potential endorsement.

9                   Next slide, 16. Finally, Draft Guide  
10 1305. This is probably the furthest one along. It  
11 deals with commercial grade dedication for design and  
12 analysis computer programs. So, that document, like I  
13 said, is furthest along. At this point it's being  
14 reviewed by OGC, so we're working with OGC to try to iron  
15 out the issues we have with that. OGC is our Office of  
16 General Counsel, our attorneys. So once we resolve the  
17 OGC comments, we will issue it and then there will be  
18 a 60-day public comment period.

19                   Next slide, 17. So, now we'll get into the  
20 meat quickly as to Part 21. Its purpose is to implement  
21 Section 206 of the Energy Reorganization Act of 1974,  
22 and Section 206 requires immediate notification to the  
23 NRC of defects and failures to comply that could create  
24 substantial safety hazards.                   And that leads us  
25 into our next slide, 18.

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1 This is a very important slide. I'd like it because it  
2 really zooms out and gives you a broad view of the areas  
3 that the staff, the working group has identified, where  
4 we've identified issues with Part 21 and we're trying  
5 to find the solutions to improve the regulations of Part  
6 21.

7 So, we split up. This first slide covers  
8 evaluation and reporting. If you look at the areas,  
9 there are 15 in total. If you look out to the right  
10 under the columns where you see the X, that just shows  
11 the combinations of solutions that the staff has  
12 identified up to this point. There are a number of  
13 these items: one, two, three, four, five, six in total  
14 where we're proposing rule language changes. For the  
15 remainder of these areas we feel that guidance, both NRC  
16 and/or industry guidance would be sufficient to resolve  
17 the issue. So today in the area of evaluation reporting  
18 you're going to hear the basis for proposed rule  
19 languages in six areas.

20 Next slide, 19. Again, so this is the  
21 commercial grade dedication half. Several areas here.  
22 Again, staff uses a combination of both proposed rule  
23 language change and NRC and/or industry guidance.  
24 You're going to hear the staff's findings in four areas  
25 here as they relate to commercial grade dedication.

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1                   Next slide, 20.    If you have had an  
2                   opportunity to look at our draft reg basis, Revision 1,  
3                   what we're doing here is just going over the layout so  
4                   you have an understanding of kind of what you'll see for  
5                   the remainder of the morning.   The way that the draft  
6                   basis is laid out, there are several chapters, six in  
7                   total, and they're split up between the evaluation and  
8                   reporting, commercial grade dedication, admin changes,  
9                   backfitting, scheduling.    But what staff is going to  
10                  present today are Chapters 2, 3 and 4, which are the  
11                  evaluation and reporting, commercial grade dedication  
12                  and then the administrative changes.

13                  Next slide.    We're still talking about the  
14                  layout for draft reg basis.   The format you'll see today  
15                  is present in the draft reg basis and in today's slides,  
16                  so I just want to lay this out so as we move through  
17                  you'll have a better feel of how -- what we'll show is  
18                  the regulatory framework currently, how the current  
19                  regulations and those other regulations that apply to  
20                  the current rule -- we'll lay that out.   Then we'll move  
21                  right into the regulatory issue.   Once we go over the  
22                  regulatory issue, we go into the proposed rule changes,  
23                  where that's a combination of -- well, we'll go into  
24                  solutions, which could be comprised of rule change  
25                  and/or NRC guidance, or voluntary industry initiatives.

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1 So that's industry guidance. That's the way the slides  
2 will be laid out.

3 Next slide, 22. That's the end of that  
4 portion.

5 Operator?

6 OPERATOR: Yes, are we taking questions  
7 and comments at this time?

8 MR. HEATH: Yes.

9 OPERATOR: All right. First make sure  
10 your phones are un-muted. To ask a question or make a  
11 comment, press star, one and record your name and  
12 affiliation when prompted. To withdraw your question  
13 or comment, press star, two.

14 Once again, for those on the phone, to ask  
15 a question, press star, one and record your name and  
16 affiliation.

17 One moment to see if we have questions from  
18 the phone. If you're taking questions from the room,  
19 I invite you to take those first and then circle back.

20 MR. HEATH: Okay. Good idea. Are there  
21 any questions from the room? Yes?

22 MR. NICHOL: Marc Nichol from NEI. First  
23 I want to thank the NRC for hosting this meeting and  
24 providing an update on what you've done and listening  
25 to stakeholder feedback.

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1           I want to make one general comment because  
2           you'll probably hear some themes from industry in our  
3           comments over the day. I think there are two areas  
4           where we have a fundamental difference in perspective  
5           on the path moving forward, and the first is in the area  
6           of the effectiveness of guidance. And so, we'd  
7           encourage the NRC to consider the effectiveness of  
8           guidance and the efficiency that guidance provides as  
9           an option to address many of these issues, especially  
10          when the purpose is to obtain clarity, which I think is  
11          a very good fit with the purpose of guidance.

12           The second area is there are actually a few  
13          proposed changes by the NRC where we actually think that  
14          there are new or changed regulatory positions that  
15          expand the scope or intent of the regulations and aren't  
16          actually clarifications themselves.

17           And so, you'll hear more detailed comments,  
18          but three main areas. One is the definition of  
19          "discovery." The other is ambiguity of the LERs,  
20          licensee's event reports under 50.72/73. And the third  
21          one is the definition of "basic component" for fuel  
22          cycle facilities.

23           So, we'd ask the NRC to further consider the  
24          proposed changes in the context of, really,  
25          clarifications we believe are actually improving the

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1 regulatory position. So, thank you.

2 MR. HEATH: Great. Thank you. Thank  
3 you, Marc. As Lisa said, we have a transcriber here on  
4 hand, so if you don't see us taking a whole bunch of  
5 notes, that's because we have them all. So again, we're  
6 not taking formal comments here, but your comment will  
7 be received and will be entertained by the staff, I  
8 assure you. But thank you for your comments, Marc.

9 Just for my information real quick, because  
10 I lost you real quick, what was the second area, Marc?  
11 The definition of "discovery" and then the use of the  
12 LERs?

13 MR. NICHOL: Yes, definition of  
14 "discovery," use of LERs, and then the definition of  
15 "basic component" for fuel cycle facilities.

16 MR. HEATH: Okay. Can you expand just  
17 real quick, Marc, on what you mean by the "LER reporting"  
18 use of --

19 MR. NICHOL: It's specific. We can get  
20 into more detail when we get to the topic, but just to  
21 give you a preview, it's specifically in the area that  
22 an evaluation under 50.72 that did not result in a report  
23 would require another evaluation under Part 21. So, I  
24 think that's where we have a different opinion than the  
25 NRC.

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1 MR. HEATH: Thank you, Marc. Any other  
2 questions from the room?

3 MR. GRESHAM: This is Jim Gresham from  
4 Westinghouse. Wondered if you could comment on your  
5 review of the NEI 14-09 and how the schedule for that  
6 review fits in with the overall schedule of the process.

7 MR. HEATH: Okay.

8 MR. PRESCOTT: This is Paul Prescott in  
9 NRO. Currently Victoria and myself are taking a look  
10 at that guidance document. What took precedence over  
11 getting too far on it right now is that as you can tell  
12 from the previous draft reg basis this was essentially  
13 a total rewrite and a change in the perspective in trying  
14 to get to the right point that we need to get to. And  
15 so, it's too preliminary at this point to give you an  
16 indication of where we think we'll go, but what I  
17 certainly have encouraged from the beginning is working  
18 with the industry on guidance documents. Hopefully  
19 we'll find this suitable and be able to find it  
20 acceptable through the Reg Guide process. That's the  
21 ultimate goal.

22 MR. HEATH: Does that answer your  
23 question?

24 (No audible response.)

25 MR. HEATH: So, we received NEI 14-09 last

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1 September. So the staff, as I stated before, is  
2 reviewing it in conjunction with the rulemaking. And  
3 we have our expert in rulemaking in the back. And as  
4 far as the schedule goes -- let me make sure I get this  
5 right. We would issue the guidance, any guidance or  
6 endorsed guidance along with the rule when the rule is  
7 promulgated. Is that correct?

8 MR. TARTAL: Yes, this is George Tartal  
9 from NRC. You're right. The Commission had directed  
10 the staff a couple of years ago to follow the effects  
11 of regulation enhancements that we made to the  
12 rulemaking process. One of those enhancement was to  
13 draft guidance along with the proposed rule and final  
14 guidance along with the final rule. So, yes, you're  
15 right that the draft guidance will be published and  
16 we'll have a concurrent comment period for the guidance  
17 along with the proposed rule.

18 MR. NICHOL: Marc Nichol from NEI. Thank  
19 you for the clarifications. I think I understand that  
20 this LER that you're talking about, but I think in the  
21 case of industry guidance that's been submitted to the  
22 NRC, since it's clarifying existing rules, it wouldn't  
23 really fall within that new rule. I think the NRC has  
24 within its discretion the ability to improve that  
25 guidance by a letter, SER, something of that nature.

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1 MR. TARTAL: This is George Tartal again.  
2 I agree with you that if we weren't in the rulemaking  
3 process, we would have the -- but because we're planning  
4 the draft guidance rule, then we'll --

5 (Technical difficulties.)

6 MR. WEAVER: Hi. Doug Weaver with  
7 Westinghouse. I guess based on the dialogue that just  
8 occurred what I'm concerned that the NEI guidance has  
9 not been considered with respect to the current rules,  
10 only being considered in the light of the rulemaking  
11 efforts that are just reg basis.

12 MR. HEATH: Repeat that?

13 MR. WEAVER: Based on what George just said  
14 and the dialogue with Mark and Paul, it sounds like the  
15 NEI guidance that's been submitted for endorsement is  
16 not being really considered in light of its guidance for  
17 the current rule that's on the books today. What we've  
18 heard is that guidance is only going to be issued in the  
19 context of the guidance for the new rule. So a major  
20 disconnect of that would be -- I mean, we expect that  
21 that guidance -- the hope was it would endorse and  
22 clarify the current rule, not to clarify the proposed  
23 new rule.

24 MR. HEATH: Okay.

25 MR. WEAVER: But I mean, from where I'm

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1 sitting listening to this dialogue it sounds like  
2 there's a disconnect in terms of the industry  
3 expectations and how NRC is treating it.

4 MR. PRESCOTT: Yes, I think, as George  
5 said, we're in a process. We have to follow the  
6 process. We don't see anything in the rulemaking  
7 that's radical and therefore would impact. As we've  
8 worked on the commercial grade dedication guidance,  
9 we've wrapped that up and essentially believe that it  
10 will be good to go, but unfortunately the staff works  
11 in a box and that box is the rulemaking box. So,  
12 unfortunately the guidance has to go with the  
13 rulemaking. Whether that's good, bad or indifferent  
14 that's not for me to say. It's just what the staff has  
15 to do. We haven't held up looking at the commercial  
16 grade dedication guidance, and the one for design and  
17 analysis is not held up, and the one for evaluation and  
18 reporting is not held up. The staff is carrying on with  
19 that along with the rulemaking process. It's just that  
20 they have to be unfortunately the way -- as George said,  
21 it's the way the process works.

22 MR. WEAVER: Yes, I understand where the  
23 guidance -- I mean, I understand why the Commission  
24 directed all the guidance with the rule. However, what  
25 we have to do is use the guidance document that was

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1 submitted alongside the rulemaking process to clarify  
2 the current rule. So, I understand where you are, but  
3 at least I got clarity on what you're thinking, although  
4 I have to say I disagree with it, because I think it's  
5 certainly, as Mark indicated, it's perfectly  
6 appropriate to clarify this current rule because it may  
7 be that rulemaking -- who knows what the Commission will  
8 do with it, right? By the time you're looking at your  
9 draft on your timeline it's several more years certainly  
10 until a final rule. If the Commission agrees, based on  
11 the feedback, you have an opportunity to get that  
12 clarity potentially much sooner. Thank you.

13 MR. HEATH: Go ahead, Marc.

14 MR. NICHOL: Marc Nichol from NEI. If I  
15 could just add to that sentiment one or two thoughts.  
16 So, and if the rule really is to provide clarity, I think  
17 the guidance is a good way to do it in the near term,  
18 which I think as the NRC pointed out, there have been  
19 some issues that really could benefit from clarity.

20 The other thing, to Doug's point about the  
21 uncertainty of the future of rulemaking, is I would  
22 point out that rulemaking clarity may have a very  
23 difficult time getting through the hurdle and the  
24 criteria of being approved for rulemaking, getting a  
25 priority. So it's feasible that it could be ten years

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1 before the rule is ever changed. And I think that's a  
2 long time to have missed out on the opportunity of  
3 providing clarity to the existing rule language. So,  
4 I urge the NRC to reconsider the path forward.

5 MR. HEATH: Thank you, Marc.

6 MR. HORIN: I'm Bill Horin with Winston &  
7 Strawn. I think what we have here is kind of a  
8 fundamental issue with the Commission's policy related  
9 to the development of guidance to go along with the  
10 rulemaking. I think what we're dealing with here with  
11 the NEI's proposed clarification document is the  
12 pre-rulemaking document doesn't fall within the policy  
13 related to rulemaking. Unless we're saying that there  
14 is no chance that this is the one option that could be  
15 selected is that we don't do rulemaking on one or more  
16 guidance documents. Then the NEI proposed guidance I  
17 think is outside the Commission's recommendations and  
18 policy that you have guidance go along with proposed  
19 rulemaking. But I think someone really needs to take  
20 a closer look at that policy and whether it's being  
21 properly applied in this instance with respect to the  
22 NEI guidance, because that is the context of not only  
23 clarifying the current rule, but addresses the question  
24 of do we even need a rule?

25 MR. PRESCOTT: And again, the staff

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1 understands this and we will certainly take back these  
2 points and weigh them with OGC, our Office of General  
3 Counsel, and the appropriate staff that are familiar  
4 with how this process works. But as far as staff here  
5 is concerned, our direction has been provided, we're  
6 moving in that path, and we'll see how it goes. Thank  
7 you.

8 MR. HEATH: Any other questions from the  
9 audience?

10 (No response.)

11 MR. HEATH: Okay. Operator?

12 OPERATOR: We have three questions from  
13 the phone. Our first question or comment comes from Ken  
14 Heffner of Certrec.

15 Your line is open.

16 MR. HEFFNER: Thank you. A quick comment  
17 about logistics first. Several people come through  
18 loud and clear. I'm not sure if other folks are not near  
19 a microphone, but there were some folks that were  
20 speaking that did not come through at all. So, I don't  
21 know if there's anything you can do about that.

22 Second comment: I'm on slide 19, if you  
23 could take a look at that for a minute. And in letter  
24 Golf, the clarification of QA requirements, none of the  
25 columns have an X in it. I'm not sure what that means.

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1 MR. HEATH: Can you repeat that, please?  
2 I'm on slide 19.

3 MR. HEFFNER: Letter golf, clarification  
4 of QA requirements. None of the columns have an X in  
5 it, which says it doesn't look like anything is going  
6 to change.

7 MR. HEATH: Oh, I'm sorry. Yes, you're  
8 correct. That was a typo. It was left off. If you're  
9 talking about Section F -- is that correct? I'm sorry.  
10 Section G?

11 MR. HEFFNER: G, golf.

12 MR. HEATH: Oh, golf? Okay.

13 MR. HEFFNER: Yes. Golf, yes.

14 MR. HEATH: Yes, NRC guidance is to propose  
15 a solution for that area. That was a typo from the  
16 original slides and I fixed it. My apology.

17 MR. HEFFNER: Okay. Thank you.

18 OPERATOR: And our next question or  
19 comment comes from Bob Link of Areva.

20 Your line is open.

21 MR. LINK: Thank you. Yes, a similar  
22 comment on the logistics aspect. It sounds like a jet  
23 engine coming in and out and then the speakers sometimes  
24 cut out entirely.

25 One, I guess, process question I've got is

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1 you mentioned the discussions today will focus on  
2 Chapters 2, 3 and 4. I guess I was questioning when and  
3 if there would be any discussion of Chapter 5 on  
4 backfitting. There was an earlier gentleman; I don't  
5 recall his name, that characterized that we didn't see  
6 anything radical. I would not agree with that  
7 characterization, at least in the fuel cycle facilities  
8 aspect, because the definition of a basic component in  
9 the equivalency of performance criteria of 70.61 to  
10 substantial safety hazard is a very significant change,  
11 and in my opinion, in a layman's term, backfit for the  
12 fuel cycle facilities.

13 So, I was wondering when and if there would  
14 be any dialogue in an open meeting on Chapter 5,  
15 Backfitting.

16 MR. HEATH: Yes, thank you for your  
17 question. To answer it, because we're in the draft  
18 regulatory basis phase, we don't go into detail into the  
19 backfitting. The level of detail that we go into is  
20 what you see in a reg basis, and the actual backfit  
21 analysis is reserved for the proposed rule phase.

22 But I encourage you to hold off and save  
23 those questions for the afternoon session, which is the  
24 fuel cycle facilities. So, we hear what you're saying,  
25 but if you could just hold off; and I'm sure you'll be

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1 present for the fuel cycle facilities, and wait until  
2 then, maybe Sabrina Atack may be able to entertain your  
3 question a little better than myself as it pertains to  
4 fuel cycles. Thank you.

5 MR. LINK: I appreciate that. I guess  
6 also as part of that where would the reg analysis, the  
7 actual cost-benefit be represented?

8 MR. HEATH: Again, the detailed analysis  
9 which would include that cost-benefit will happened in  
10 the proposed rule phase once the draft reg basis is  
11 finalized. So, that's the next phase of the  
12 rulemaking.

13 MR. LINK: Thank you.

14 MR. HEATH: Yes.

15 OPERATOR: No further questions from the  
16 phone.

17 MR. HEATH: All right. Thank you,  
18 operator.

19 All right. I thought we had a break, but  
20 we don't have a break, so what we'll do is run right into  
21 Chapter 2, which covers the evaluation and reporting  
22 piece of Part 21. Again, what you'll hear today is  
23 discussion in only those areas where we're proposing  
24 rulemaking.

25 The first is Section 4. And I'm on slide

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1 25, and this is clarification of "discovery." So what  
2 do the regulations say about clarification of  
3 "discovery?"

4 Next slide, 26. So "discovery" means  
5 -- and I'll just read it. I won't try to abbreviate.  
6 "Discovery" means the completion of the documentation  
7 first identifying the existence of a deviation or  
8 failure to comply potentially associated with a  
9 substantial safety hazard. Keeping in mind that a  
10 deviation is what, it's a departure from a technical  
11 requirement. So upon discovery of a deviation, an  
12 evaluation for defect must be performed under 21.21(a).  
13 And that must be completed within 60 days. So  
14 it sounds very simple, straightforward. When a defect,  
15 when a deviation is identified, then that constitutes  
16 what will be the discovery. And then you have 60 days  
17 for which to complete your evaluation.

18 And I guess I'll use a simple example for  
19 today. The Licensee's procured a widget. The widget  
20 is supplied with installed fuses. An engineer  
21 identifies, let's say January 1st, that the component  
22 came with improperly sized fuses. All right?  
23 Engineer discovers on January 1st the widget has some  
24 improperly supplied fuses. So the deviation in this  
25 example would be the improperly sized fuses, not in

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1 accordance with what the licensee indicated on the  
2 purchase order. All right? So there's your  
3 deviation.

4 Next slide, 27. So the problem with  
5 discovery as we see it is there is no regulatory  
6 requirement that limits the time period between the  
7 initial identification of the issue, or the deviation,  
8 and the completion, "the completion," in quotes, of the  
9 documentation constituting discovery. All right?

10 So the staff through our inspections over  
11 time we've noticed a number of instances where there's  
12 an inordinate amount of time that passes between the  
13 point at which the vendor or supplier or licensee has  
14 had enough information to make a determination that a  
15 deviation exists and the date of discovery is actually  
16 recorded. Right? We've seen that as a problem over  
17 time.

18 So, if we go back to our widget example, our  
19 widget with the fuses, the deviation is improperly sized  
20 fuses that were discovered by an engineer on January  
21 1st. Okay? The licensee may perform some type of  
22 evaluation and then we find that the documentation date  
23 for discovery is February 1st, a month later. All  
24 right? That's not the way that -- that's not the  
25 staff's position on discovery. Right?

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1           So, our expectation, the NRC position is  
2           that the supplier/purchaser/licensee should take  
3           action without delay to confirm if a deviation exists  
4           and not wait to complete some exhaustive analysis to  
5           determine -- before they enter that condition into a  
6           Corrective Action Program; i.e., you identified an  
7           issue on the 1st of January and the discovery date for  
8           that issue got recorded on February 1st because the  
9           licensee/vendor/supplier took a week, two weeks, three  
10          weeks, a month to do some analysis and evaluation to  
11          determine if this is a potential safety hazard. And  
12          then therefore some time period for it -- you record the  
13          discovery date once your evaluation is completed. Part  
14          21 does not afford you that time period that we've seen  
15          licensees/vendors/buyers take.

16                 So, next slide, 28.     So there's a  
17          misconception about when discovery occurs. One of  
18          those misconceptions is that discovery does not occur  
19          until your Part 21 evaluation begins. That's your  
20          21.21(a) evaluation. All right. The NRC's position  
21          again, as I said before, is that once you identify  
22          deviation, you should not delay and wait to perform some  
23          exhaustive evaluation before you enter that issue into  
24          your Corrective Action Program and document discovery.  
25          Okay?

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1           So, what is true and the staff's position  
2           is that discovery actually occurs when there's enough  
3           information to determine that a defect exists.

4           I'm sorry. Thank you, Paul. Discovery  
5           occurs when there's enough information to determine  
6           that a deviation exists.

7           One of the other misconceptions is, next  
8           slide, and I'm on 29, within the definition of  
9           "discovery" there's been misconceptions about the term  
10          "potentially associated with a substantial safety  
11          hazard." That term is commonly misapplied. And the  
12          staff position is that any evaluation period necessary  
13          to determine if a potential safety hazard exists should  
14          occur independently of discovery.

15          Again, that goes back to our widget  
16          example. Engineer identifies the issue on January 1st.  
17          There's no evaluation that takes a month that ends on  
18          February 1st, and then February 1st becomes your  
19          discovery date. If it was identified, the deviation  
20          was identified on January 1st that the fuses and the  
21          widget were wrong and not what was requested on the PO,  
22          then that should be the date of discovery. That is the  
23          staff's position.

24          Our next slide. I'm on 30. So, the  
25          changes that we're proposing in the area of discovery

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1 is a revision of the definition. All right? So  
2 discovery becomes the first -- is the first  
3 documentation of the deviation in a formal process.  
4 That is straightforward. But you have to do it right.  
5 So, the important change that we're proposing is, as I  
6 stated before in the previous slide, is when it is  
7 determined that there's enough evidence collected that  
8 a deviation exists, that deviation should be documented  
9 and that time becomes discovery. That's what the staff  
10 is going to propose moving forward.

11 And we're at the end of that section, slide  
12 31. So I will open it up to questions on the floor  
13 first.

14 MR. LOOMIS: My name is Tom Loomis. I'm  
15 the chairman for the Part 21 Task Force for the industry.  
16 And, Jermaine, your issue of the widget is absolutely  
17 perfect, and we in the field see that often, was that  
18 idea that part would fail if the fuse was the wrong size.  
19 We have no problem with getting started on day one. The  
20 reality is though often you have to get into a  
21 post-mortem and that requires weeks of evaluation at  
22 that point. Then you would be able to say, say three  
23 weeks later, once we send it off, then we would have  
24 enough information to say, yes, that's a part by which  
25 we have Part 21 defects and we can begin a corrective

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1 action plan three weeks into it. We cannot do it on  
2 which we do not have the IR. And that's basically where  
3 we sort of part ways as far as our thinking on when you  
4 enter into the system versus the fact of when you declare  
5 the Part 21. And so, that's a classic example where we  
6 part ways. Does that make sense?

7 MR. HEATH: Yes. Tom --

8 OPERATOR: Excuse me. This person was not  
9 mic'd. Could you mic that person and repeat their  
10 question?

11 MR. HEATH: Oh, we may be having an  
12 audio/video issue.

13 MR. LOOMIS: Do I need to be closer then?  
14 Okay.

15 MR. HEATH: Operator, is he okay?

16 OPERATOR: Have him take one step back and  
17 we can try to resolve.

18 MR. LOOMIS: Okay. Now?

19 OPERATOR: Move closer, please.

20 MR. LOOMIS: Okay. Can you hear me now?

21 OPERATOR: Let's try.

22 MR. LOOMIS: Let me repeat the example  
23 again. The example of the widget is the classic issue  
24 of a Part 21. If our people in the field could see on  
25 that day one that that was the wrong sized fuse, they

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1 get it into the corrective action system, we got no  
2 problem with the fact of entering that starting the Part  
3 21 at that point. The reality of it is, is if you have  
4 a part that fails in the system; let's take an outage  
5 situation, you'll initiate that IR, that corrective  
6 action on that spot, but you will take and you will send  
7 that part off for a post-mortem. It may take two, three  
8 weeks to get something back on that. So when do you  
9 start the Part 21 evaluation on that? I think  
10 the staff in many respects would want you to date it back  
11 to when that part failed in the field. In our case we  
12 would think that you would wait two weeks, once you do  
13 your post-mortem. And at that point you have the  
14 information to say, yes, that's definitely a  
15 manufacturer's defect. We're just not that quick out  
16 in actuality. I mean, does that point make sense?

17 OPERATOR: And that was loud and clear.  
18 Thank you.

19 MR. HEATH: Thank you, Tom. Yes, your  
20 point is well taken and understood, but if you go back  
21 to slide 30, I'll point back to the change. The other  
22 piece of that is what the staff is proposing and what  
23 we're expecting is when it is determined that you have  
24 enough evidence collected, that is your discovery date.  
25 That's the difference. So, I understand, we understand

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1 your concern.

2 MR. LOOMIS: Right.

3 MR. HEATH: Yes, if that involves sending  
4 the part off, the widget, to do a post-mortem and you  
5 don't have to have enough -- when the staff determines  
6 you have enough evidence, that should be your recorded  
7 date.

8 MR. LOOMIS: Okay. So, we would be  
9 allowed to post-mortem on that then?

10 MS. CLARK: You have to be back on the mic.  
11 Sorry.

12 MR. LOOMIS: So, we'd be allowed to  
13 post-mortem on that? We'd be allowed those couple of  
14 weeks to go out there and diagnose that problem before  
15 we would be getting the Part 21 evaluation started?  
16 That's what I'm hearing you say. That's a yes?

17 MR. HEATH: See, I'm careful to speak  
18 absolutely, but remember what a "deviation" is defined  
19 as currently: a departure from a technical requirement.

20 PARTICIPANT: Of the  
21 procurement document.

22 MR. HEATH: Of a procurement document,  
23 correct. So, if you have enough information --

24 MR. LOOMIS: You're not going to know that  
25 up front.

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1 MR. HEATH: So again, the definition, what  
2 we're proposing to change is once you have enough  
3 evidence to determine that the deviation exists, that  
4 shall be your recorded discovery date.

5 MR. LOOMIS: Okay. Now, and just to  
6 reiterate here where the industry is on this again,  
7 being as the chair of the task force on Part 21, we feel  
8 as though we can hash this all out with a guidance  
9 document. We feel as though you can enforce it, the  
10 guidance document. But we feel that the rulemaking is  
11 not necessary. Rulemaking is going to create a lot of  
12 confusion. And when we were going through your  
13 preliminary slides at our pre-meeting yesterday, we  
14 were just as confused as what it would be as if you issued  
15 the rule. We did not have the clarity I think you folks  
16 are looking for.

17 That's why we offered to sit down. We'll  
18 go through the document with you line by line to make  
19 sure that we have complete agreement on where we were  
20 on the guidance document. That's why you'll hear our  
21 continuous theme here of the new -- of our NEI document  
22 hoping that you'll sit with us and hash it out rather  
23 than go through the rulemaking. That's kind of our  
24 position. You'll hear that theme today. Thanks.

25 MR. HEATH: Thank you, Tom. Yes, Marc?

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1 MR. NICHOL: Marc Nichol from NEI. So I  
2 want to ask a point of clarification because I'm not sure  
3 I exactly understand. So, SECY-91-150 is the NRC  
4 policy and has some statements about discovery in there.  
5 It acknowledges that sometimes discovery takes a little  
6 bit of time, from first identifying the problem to  
7 actually knowing that it's a deviation.

8 What I think I'm hearing today is the NRC  
9 still agrees with that SECY, that discovery may take  
10 some time from initial identification of a problem to  
11 identify a deviation. So I want to make sure that I'm  
12 correct in that understanding, because when I look at  
13 Revision 1 of the draft basis, I don't get that  
14 impression. So, could you tell me if I'm correct in my  
15 understanding?

16 MR. HEATH: You say you didn't get that  
17 impression from Revision 1?

18 MR. NICHOL: Right. Revision 1 of the  
19 draft regulatory basis to me -- I interpreted it to mean  
20 that the staff does not agree with SECY-91-150 that a  
21 discovery occurs as soon as you identify a problem,  
22 whether or not you have the evidence to know it's a  
23 deviation. But I think what I'm hearing in the meeting  
24 today is not consistent with my understanding of the reg  
25 basis.

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1 MR. HEATH: Our position is based on the  
2 evidence.

3 MR. NICHOL: So you still agree with  
4 SECY-91-150?

5 MR. HEATH: I think that's fair.

6 Yes?

7 MR. DUNKELBERGER: Mike Dunkelberger from  
8 MPR. Just to go back to your analogy then, the widget  
9 fails on January 1. It takes two weeks to find out that  
10 the reason it failed is that fuse is undersized. You  
11 enter it into your Corrective Action Program on the date  
12 that the widget failed. Two weeks later you realize  
13 there is a deviation this -- using the widget is  
14 undersized. The point of discovery is the date that you  
15 determine the fuse is undersized, not the date you first  
16 wrote it in your Corrective Action Program?

17 MR. HEATH: That would be correct, yes.

18 MR. DUNKELBERGER: Okay. Thank you.

19 MR. HEATH: If I was not clear on that part,  
20 I apologize. But, yes, your statement is correct.

21 MR. DUNKELBERGER: Yes, to echo Marc's  
22 concern, understanding the intent of the reg basis,  
23 that's why the guidance is so important, because just  
24 knowing the history of how Part 21 has been interpreted,  
25 even with the proposed changing the language and even

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1 the discussion in the reg basis, there are still some  
2 who are interpreting, oh, the date I wrote the CR is the  
3 date that Part 21 clock begins, and that we're finding  
4 we're in agreement that that's not always the case.

5 MR. HEATH: Thank you.

6 MR. PRESCOTT: This is Paul Prescott of the  
7 staff, NRO. To answer that question I think this points  
8 out clearly why we believe for this particular item  
9 rulemaking is such a necessity. It has been a thorn in  
10 the side of the industry and ours for as long as I've  
11 been doing this. We've gone to OGC multiple times to  
12 get a discussion on this, about what discovery is, when  
13 the point is. And we've had issues from various  
14 inspections. We've had issues with calls to us on am  
15 I in the discovery phase or am I in the evaluation phase?

16 So, I think this one especially speaks to,  
17 at least to me, that rulemaking is necessary to clarify  
18 it.

19 To go back to, well, if we clarify it in the  
20 guidance, that's going to be sufficient, a regulatory  
21 standpoint, no. No, we as the staff cannot go and quote  
22 guidance documents in a Notice of Nonconformance or  
23 Violation that you've done something wrong. We have to  
24 take it back to the regulation. The guidance alone  
25 sometimes is not sufficient. Thank you.

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1 MR. CASTELL: Curt Castell, Chicago Bridge  
2 & Iron. In your clarification have you considered  
3 adding a definition of "failure to comply" to the  
4 regulation?

5 MR. HEATH: No, it has previously been  
6 defined. I can't quote the document.

7 PARTICIPANT: Under the Statements of  
8 Consideration. Through a regulation order. That's  
9 defined.

10 MR. CASTELL: Right. Had you considered  
11 adding it to the regulation though so we have  
12 completeness of definitions in the regulation?

13 MR. PRESCOTT: Certainly we absolutely  
14 could take that into consideration. Thank you.

15 MR. CASTELL: Okay. Thanks.

16 MR. LOOMIS: Paul, it's Tom Loomis from  
17 Exelon again.

18 MR. PRESCOTT: Yes, sir.

19 MR. LOOMIS: I'm going to take issue with  
20 here --

21 MR. PRESCOTT: Okay.

22 MR. LOOMIS: -- with regards to the idea of  
23 revising the rule on this.

24 MR. PRESCOTT: Okay.

25 MR. LOOMIS: I mean, we deal with

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1 NUREG-1022 on reporting requirements, correct? I  
2 mean, basically it's a NUREG how we interpret it. I'm  
3 just kind of wondering why we can't do the same thing  
4 with the NEI document. Because we're sort of looking  
5 at the rule and we're saying this is the rule, this is  
6 the way the rules works, this is how it says. We're  
7 really not disagreeing with the way in which the rule  
8 is written as is. Here's a clarification as we see it.  
9 And I think Jermaine's example here, as a matter of fact,  
10 on the widget is one of the examples we have in the NEI  
11 document.

12 And so, I really think we can use the  
13 clarification document where you can enforce against it  
14 and say, hey, you guys agree that this is the way the  
15 rule reads through the NEI document, therefore we're  
16 going to cite you on that. We have no problem with you  
17 citing with those people who have not been following the  
18 rule. Part of what we want is we want good compliance.  
19 We, as the licensees, the people out there. We want to  
20 follow the rules. That's what our objective is. We  
21 feel as though we can have you cite against the rule and  
22 interpreting it through the NEI document. And again,  
23 that's why we think as though we could hash this out in  
24 a couple of months and be done with this and everyone  
25 comes to a good agreement on it. So, I just wanted to

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1 point that out. Now I'll let you move ahead.

2 MR. HEATH: All right. Thank you. What  
3 I'd ask, if you can -- is it possible you can hold your  
4 question? We're running a little behind schedule.

5 PARTICIPANT: We'll keep you awake.

6 (Laughter.)

7 MR. HEATH: Okay. Operator, is there  
8 anyone on the phone?

9 Again, people, we have our open discussion  
10 period right after lunch. This is 45 minutes on this,  
11 but we're running just a little behind this morning.

12 OPERATOR: You have three questions from  
13 the phone. Can we take questions at this time?

14 (No audible response.)

15 OPERATOR: We have Nick Serafin. Your  
16 line is open.

17 MR. SERAFIN: The question has been asked  
18 and answered. Thank you.

19 OPERATOR: All right. We have Adam  
20 McCartney. Your line is open.

21 MR. MCCARTNEY: Good morning. I would  
22 just like to echo the comment of defining "failure to  
23 comply." There is plenty of emphasis on deviation, but  
24 I think we're lacking on failure to comply. That's all.  
25 Thank you.

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1 OPERATOR: And a follow-up from Bob Link of  
2 Areva.

3 MR. LINK: Yes, I guess it's more of a  
4 comment or a suggestion. I do agree with the other  
5 industry representatives that I think this could be  
6 taken care in the guidance. I'm not that familiar with  
7 the NEI document, but the more examples that could be  
8 presented in a guidance document, the better typically  
9 in terms of a cohesive understanding.

10 And while I understand your example with  
11 the widget, it gets even more complex when you have a  
12 vendor, and even perhaps a commercial grade dedicated  
13 item in terms of when you get information and when it  
14 becomes discovery in the context of Part 21. And you  
15 may even have a second tier vendor that has a materials  
16 issue that is then just notified up the food chain, so  
17 to speak.

18 So, any and all examples that would include  
19 those kind of permutations would be highly valuable, but  
20 I do agree that this issue could be dealt with through  
21 guidance.

22 MR. HEATH: Thank you.

23 MR. HORIN: And I apologize. This is Bill  
24 Horin with Winston & Strawn. Just in case we're not all  
25 around for the question period, I just want to point out

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1 that one element of your example I think is  
2 fundamentally flawed, and that goes to the first and  
3 third bullets on page 3. A licensee employee who sees  
4 that a fuse is blue when they're used to seeing -- has  
5 a blue label on it when they're used to seeing a red label  
6 is encouraged to put that finding into the system. It  
7 may turn out that it's simply the manufacturer's changed  
8 label colors. But they put that into the system.

9 And by hanging your hat on putting it into  
10 the corrective action process is just totally  
11 disassociated with what we're supposed to be dealing  
12 with here. And I think given some of the clarification  
13 here this morning, I think we better understand what  
14 you're thinking, but the first and third bullet are not  
15 correct.

16 MR. HEATH: No, I think there may be a  
17 little bit of -- it might have been my fault as I was  
18 drafting these slides, but, no, I'm agreeing with you.  
19 And the meat of this is, as I stated before, based upon  
20 the evidence collected. So, no, identifying the blown  
21 fuse the day that it's identified and putting it in the  
22 Corrective Action Program becomes your discovery date.  
23 Again the staff understands, and our position is that  
24 there may be some evidence that you have to collect.  
25 There may be a window. So, I think along the way the

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1 slides read maybe I could have probably could have done  
2 that, but I don't think I'm disagreeing with your  
3 position.

4 All right. So, I'll ask if we can just hold  
5 questions and we can just move along. We're going to  
6 have time at the end of the morning session to take a  
7 couple questions if I end early before lunch, but let's  
8 move along to the next area.

9 So, we're in Section 5 of the reg basis,  
10 slide 32, which covers the clarification of "defect."

11 Next slide, 33. So the existing  
12 regulatory framework for defect, if you look back at  
13 NUREG-0302, you'll see that there are multiple  
14 definitions of -- the mic's on?

15 OPERATOR: You were fading in and out.

16 MR. HEATH: Operator, can you hear me?

17 OPERATOR: Loud and clear.

18 MR. HEATH: Okay. Can you hear me in the  
19 back?

20 OPERATOR: Also loud and clear.

21 MR. HEATH: Okay. So if you look back to  
22 NUREG-0302, you'll see that there are multiple  
23 definitions of "defect" created to capture a host of  
24 different entities when you look at the definition of  
25 "defect." So, defect applies to a number of entities

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1 off-site, on-site suppliers, purchasers and licensees.  
2 So when you go to 21.3, defect applies to all of these  
3 things that apply, to all of these different entities.  
4 And what do we do with them? There's been confusion out  
5 in the industry; if we could go to the next slide, 34,  
6 as to which definition applies to you. So, what we have  
7 here; and I'll just go back one, but this just shows the  
8 five definitions of "defect." And our point here is  
9 that the multiple definitions have created confusion in  
10 the industry and how those apply.

11 So, if we go to slide 35, the regulatory  
12 issue at hand is that -- and this is just one example  
13 of the confusion that the many definitions create. If  
14 you look at the second definition of "defect," it uses  
15 the terms "installation, use or operation of a basic  
16 component." All right? This has led some to believe  
17 that a deviation identified in the basic component that  
18 has been delivered cannot be a defect unless it's been  
19 installed or is currently in use. All right? That's  
20 false. Right? That's not the staff's position. All  
21 right?

22 What is true -- I'm on slide 36. So what  
23 is true is that if a basic component has been delivered  
24 and a deviation is identified in the basic component,  
25 that component does not have to be installed or

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1 currently in use. That component still needs to be  
2 evaluated under 21.21(a). Right? That's just one  
3 example of the confusion that the many definitions of  
4 "defect" create.

5 So, if we move forward on to slide 38, what  
6 we're proposing is to simplify the definition of  
7 "defect." We want to create one definition of "defect"  
8 under Part 21. And "defect" is simply going to mean,  
9 for clarity's sake, is a defect will become a deviation  
10 in a basic component delivered to a purchaser that could  
11 create a substantial safety hazard. So, there's one  
12 definition of "defect" under Part 21. All right?

13 In addition, we're proposing to add a  
14 definition for "delivery" to Part 21, and that will be  
15 covered in the next section of the presentation. Any  
16 questions on the definition of "defect" from the  
17 audience?

18 MR. NICHOL: Marc Nichol, NEI. I'll make  
19 it brief because I know we're falling behind schedule,  
20 but industry disagrees with the NRC on this one. We  
21 think the definition as it exists now has actually  
22 provided clarity, not the opposite effect. And we  
23 think that the NRC's proposed change would actually  
24 reduce clarity and because each of those definitions  
25 provide additional information and capture nuances in

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1 how Part 21 is applied to different types of licensees.  
2 For example, definition 3 which applies to facilities  
3 under construction, early site permits.

4 It's not captured in your definition on the slide,  
5 but there's a concept in there of any portion of the  
6 facility pertaining to deviation has been offered to the  
7 purchaser. So offered to the purchaser is a very  
8 important concept for these facilities/ESPs under  
9 constructions that would not be captured in the proposed  
10 definition from the NRC. So, we think that the NRC's  
11 proposed change would have the opposite effect of your  
12 intent.

13 MR. HEATH: Thank you, Marc. Any  
14 questions from the audience? Comments?

15 (No response.)

16 MR. HEATH: Operator, phone?

17 OPERATOR: Bob Link from Areva, your line  
18 is open.

19 MR. LINK: Thank you. Maybe it's just a  
20 reiteration of the last comment, but I find this  
21 definition, at least for fuel cycle facilities, to be  
22 difficult to interpret. And we'll get into it I know  
23 later on this afternoon in terms of what and when an item  
24 becomes a basic component, because under our mechanisms  
25 many times, if not all the times, we can't even have a

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1 basic component until we have installed it and have done  
2 testing of that device for its safety function in place.

3 MR. HEATH: All right. Thank you for your  
4 comment. Again, we'll --

5 OPERATOR: This is the operator. We lost  
6 audio momentarily.

7 MR. HEATH: Can you hear me?

8 OPERATOR: Loud and clear. We have one  
9 further question. Does time permit?

10 MR. HEATH: Go ahead. We'll take one  
11 more.

12 OPERATOR: All right. Sidney Bernsen,  
13 your line is open. Please make sure your phone is  
14 un-muted.

15 MR. BERNSEN: Hello. I have a general  
16 observation which disturbs me. I think the fundamental  
17 purpose of Part 21 was to get information from people  
18 providing components that may affect one or more plants.  
19 There's plenty of reporting requirements for plants in  
20 operation and plants under construction in existing  
21 regulations.

22 I wonder, Jermaine, have you seen the  
23 papers that I sent you last week? I hope perhaps you  
24 guys consider them in the future. I have a lot of  
25 general observations.

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1 I think you're putting too much emphasis on  
2 Part 21 into the licensee and the operating or  
3 construction phase.

4 MR. HEATH: Yes, your documents have been  
5 viewed, but I did receive your documents.

6 OPERATOR: Mr. Bernsen, any further  
7 comment?

8 MR. BERNSEN: No.

9 OPERATOR: All right. No further  
10 questions from the phone.

11 MR. HEATH: Thank you. So we'll move on to  
12 the next section, Section 6. Delivery is the next area  
13 where we're proposing rule change. Slide 40. This is  
14 not delivery when you look at this icon, cute as it may  
15 be. I don't think anyone is, but if you think it is -- if  
16 this is your idea of delivery, you would be let down.

17 Next slide. So, the existing regulatory  
18 framework for delivery, the concept of delivery is  
19 contained in defect. There is no definition of  
20 "delivery" under the current regulation, but what does  
21 "delivery" mean?

22 Forty-two. As I said before, there's no  
23 definition for "delivery" in the current regulation.  
24 So, delivery is very important. It represents the  
25 transfer of ownership between purchaser and supplier.

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1 Also includes -- that deals with the -- important in that  
2 is the transfer of ownership of the Part 21 reporting  
3 responsibilities.

4 So, what does transfer of ownership look  
5 like? That's very important, and it's not clear of  
6 where that delineation occurs.

7 Slide 43. So, delivery applies when a  
8 basic component has been received by a purchaser through  
9 a formal acceptance process. That's normally a receipt  
10 inspection. So, for basic components that have not  
11 been delivered, there is no Part 21 potential. Basic  
12 component has not been delivered, there is no Part 21  
13 notification potential. That wasn't clear. Why?  
14 Because there is no substantial safety hazard. Cannot  
15 have a substantial safety hazard and basic components  
16 that have not been delivered to the purchaser.

17 Next slide, 44. What are we proposing?  
18 We're proposing to add a definition of delivery to Part  
19 21 and clearly define the transfer of ownership -- or  
20 clearly define the transfer of reporting responsibility  
21 between the purchaser and supplier. So the point of  
22 delivery is the dividing line of the reporting between  
23 the purchaser and the supplier. Evaluations of  
24 deviations or failures to comply are only required in  
25 those items that have been delivered. We feel

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1 like this will reduce the burden on both the purchaser  
2 and supplier, keep them, the purchaser and supplier from  
3 performing unnecessary evaluations in basic components  
4 that have not been delivered. 21.21(b) is going to  
5 remain the same. So if the supplier determines that  
6 they don't have enough information or the capability to  
7 perform their 21.21(a) evaluation, it will still be  
8 required to inform the purchaser within five days.

9 So, recap really clear, the new definition  
10 of "discovery" the staff is going to propose is that  
11 "delivery" means that the purchaser has accepted a basic  
12 component through a formal process.

13 End of Section 6. Any questions from the  
14 audience?

15 MR. NICHOL: Marc Nichol, NEI. Generally  
16 we agree. I have one slight concern on slide 43. It  
17 would be the second sub-bullet where it's saying after  
18 delivery Part 21 evaluation reporting responsibilities  
19 transfer from the supplier to the purchaser. I don't  
20 know if it's the NRC's intent, but the way I would  
21 understand that statement is that once the part  
22 transfers -- is accepted by the purchaser, the supplier  
23 no longer has responsibility to evaluate and report. I  
24 don't believe that's the current regulation. I don't  
25 know if that's what the NRC intends, but that's the way

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1 I've interpreted it, and others could as well. So, it  
2 could be confusing. And you may want to consider that  
3 and try to clarify that in your final reg basis what your  
4 intent there is.

5 MR. HEATH: Thank you, Marc.

6 More questions or comment from the  
7 audience?

8 MR. WILLIS: This is Fred Willis with  
9 Southern Nuclear. I have a question. This seems to be  
10 a departure from the offer for use context of how  
11 delivery occurs. And so, from my standpoint in  
12 construction I can see a confusing situation where a  
13 component is shipped to the site but hasn't gone through  
14 the formal receipt inspection process, however, a  
15 deviation has been identified. It's been known that  
16 there's a deviation that exists. They can hang out in  
17 limbo for quite some time.

18 With the new proposed definition I think  
19 there's a lot of confusion from my standpoint on how that  
20 applies.

21 MR. HEATH: Okay. In your example you  
22 have a component on site that hasn't -- a deviation has  
23 been identified but you have not accepted the component.

24 MR. WILLIS: Per the proposed rule, yes,  
25 the receipt inspection has not taken place.

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1 MR. HEATH: So according to the proposed  
2 rule the supplier will bear the Part 21 responsibility  
3 in that example.

4 MR. WILLIS: I'm sorry. Can you say that  
5 again?

6 MR. HEATH: In your example along with the  
7 proposed rule the supplier would bear the Part 21  
8 reporting responsibility because that item has not been  
9 accepted by the purchaser through a formal process  
10 evaluation and inspection.

11 MR. WILLIS: So, but it hasn't been  
12 delivered. And so, when you go to 21.21, the concept  
13 of evaluation inherent to that is delivered and  
14 accepted. So, nobody has accepted that component.

15  
16 MR. PRESCOTT: As anyone who's dealt with  
17 Part 21 for a long time knows, there's been a long  
18 history of when a basic component is just that, a basic  
19 component. And why do I talk about basic components in  
20 delivery? Well, there wouldn't be a separate part  
21 here. It all goes together.

22 The issue at hand -- and we've gone to OGC  
23 multiple times, the staff has gone to OGC multiple times  
24 to get clarification of when this occurs. And the  
25 opinion has been that -- the staff's position has been

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1 that if it's been delivered and accepted by the  
2 licensee, then it is a basic component at that time.

3 The issue of course is then -- then the  
4 football gets passed back and forth. Well, you have  
5 reporting responsibility. No, I have reporting  
6 responsibility. Well, that's why we call it -- that's  
7 why we had to go to OGC to get a decision on this. And  
8 the current staff position; and it's this been this way  
9 for a long time, is that if the licensee has accepted  
10 it, then it's their responsibility. Obviously, we  
11 would hope that the two parties work together to resolve  
12 these, and it will probably will take that, but when it  
13 comes down to the wire about who has the final decision  
14 on what to do, that's been the call.

15 MR. WILLIS: The proposed rule change  
16 isn't going to clarify?

17 MS. CLARK: Can you hear? Could you  
18 speak --

19 MR. WILLIS: Yes. Okay. I think that's  
20 on now. Hello. This is Fred Willis again.

21 MS. CLARK: Operator, could you hear that?

22 OPERATOR: Loud and clear.

23 MS. CLARK: You hear that? Okay. Good to  
24 go.

25 MR. WILLIS: Based on what you said,

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1 Paul --

2 MR. PRESCOTT: Yes.

3 MR. WILLIS: -- I think this is why this is  
4 an example of why this issue needs to be resolved through  
5 guidance and not rulemaking, because with the proposed  
6 changes in the Rev 1 of the draft reg basis, for me  
7 there's a lot more confusion than there was  
8 clarification.

9 MR. PRESCOTT: Okay.

10 MR. WILLIS: Because I understand what you  
11 all were presenting here earlier, but based on the  
12 proposed changes in the back of the Rev reg basis  
13 document, it just muddies the waters even more.

14 MR. PRESCOTT: And these issues have been  
15 taken down and we're taking that comment back. And  
16 believe me, we're going to weigh these comments, but  
17 where we're not coming from is the historical  
18 perspective of the issue that we've had with delivery  
19 and when something is declared a basic component. So  
20 again, I hear you and again we'll take it back for  
21 consideration. But again, I'm just trying to give the  
22 staff's position on why we're at where we're at with  
23 this.

24 MR. WILLIS: Thanks. And I absolutely  
25 agree that needs to be clarified.

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1 MR. HEATH: We need to catch up.  
2 Operator?

3 OPERATOR: Operator here.

4 MR. HEATH: We have anyone on the phone?

5 OPERATOR: We have four questions from the  
6 phone.

7 MR. HEATH: Four questions from the phone.  
8 Okay.

9 OPERATOR: First question, Michael Leahy.  
10 Make sure your line is open.

11 MR. HEATH: Operator, can you hold on the  
12 questions? We're going to go ahead -- since we've been  
13 running long and we're running behind, we're going to  
14 go ahead and take a break. Hopefully those people on  
15 the line and those in the audience will come back after  
16 lunch and -- right, for that discussion period. Once  
17 we get there, we'll try to field some of those questions  
18 there. But we're trying to move through the schedule  
19 this morning. So, we're going to go ahead and give  
20 people a break.

21 OPERATOR: Copy that.

22 MR. HEATH: Copy that. Ten minutes? All  
23 right. So let's go ahead and take 10 minutes.

24 (Whereupon, the above-entitled matter went  
25 off the record at 10:33 a.m. and resumed at 10:47 a.m.)

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1 MS. HUCKABAY: Okay. So we are moving on.  
2 My name is Victoria Huckabay and for the next few minutes  
3 we'll talk about two additional sections of our Revision  
4 One of the draft regulatory basis. I'm on Slide 46,  
5 Section 9, Use of Licensee Event Reporting and CFR 50.72  
6 and 50.73.

7 On Slide 47 the existing regulatory  
8 framework you have a couple bullets here in front of you.  
9 We are looking at the 10 CFR 21.1, the purpose section,  
10 which states that the regulations in this part establish  
11 procedures and requirements for the implementation of  
12 Section 206 of the Energy Reorganization Act of 1974.

13 That paragraph furthers states that any  
14 individual director or responsible office is required  
15 to notify the Commission of a defect or failure to comply  
16 unless he, such as the individual director or an  
17 officer, has actual knowledge that the Commission has  
18 been adequately informed of such defect or failure to  
19 comply.

20 Further, 10 CFR 21.2(c) that paragraph  
21 states that for persons licensed to operate the nuclear  
22 power plant under Part 50 or Part 52 of this chapter,  
23 Evaluation of Potential Defects, and appropriate  
24 reporting of defects under Sections 50.72, 50.73 and 73

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1 - or excuse me, or 73.71 of this chapter satisfies each  
2 person's evaluation, notification, and reporting  
3 obligation to report defects under this part and the  
4 responsibility of individual directors and responsible  
5 officers of these licensees to report defects under  
6 Section 206 of the Energy Reorganization Act of 1974.

7 Right. So on Slide 48 you have a partial  
8 quote from that paragraph on 10 CFR 21.2(c). The  
9 regulatory issue as shown here on Slide 49 we are  
10 highlighting a couple of issues such as an inconsistent  
11 approach by licensees on whether only an evaluation or  
12 an evaluation and a reporting of potential defects  
13 satisfies Part 21 evaluation and the reporting  
14 obligations.

15 The NRC staff found over the years that  
16 licensees are inconsistent in their approach on whether  
17 only an evaluation or an evaluation and reporting of a  
18 potential defect under Part 50 will discharge their Part  
19 21 evaluation and reporting obligations.

20 The intent of the rule amendment to 1991 was  
21 to reduce duplicate instances of reporting such as  
22 reporting a defect under both Part - excuse me, Section  
23 50.72 or 50.73 and reporting these same under Part 21.

24 However, the intent of that rule amendment

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1 was not to relieve the licensee of the obligation to  
2 evaluate and report a defect or failure to comply.

3 And as we noted in the document - our  
4 document, the draft reg basis, there were multiple  
5 examples of licensee event reports, which we have  
6 identified that met the criteria for 10 CFR 50.72 or  
7 50.73 but the identification of potential 10 CFR Part  
8 21 issues was not satisfied.

9 On Slide 50, proposed changes to the  
10 regulations with regard to the use of licensee event  
11 reports, the NRC staff is considering correcting the  
12 regulatory ambiguity by clarifying the statements in 10  
13 CFR 21.2(c) to indicate that the reports of defects  
14 under 10 CFR 50.72, 50.73 or 73.71 of this chapter  
15 satisfies each entity's evaluation, identification and  
16 reporting obligation under this part. We know that the  
17 staff is not proposing the modification of any of the  
18 current requirements of 10 CFR 50.72 or 50.73 nor are  
19 we proposing any changes to NRC guidance on how to meet  
20 10 CFR 50.72 or 50.73, which is currently found in  
21 NUREG-1022 Revision 3 and a Supplement 1. And we are  
22 now in Slide Number 51 and I am ready to take your  
23 questions with regard to LERs and first we're going to  
24 take some questions from the audience here. So

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1 Operator, please stand by.

2 MR. LOOMIS: Hi, Victoria, it's Tom Loomis  
3 from Exelon again and if I'm understanding the issue  
4 here is this a simple check at the box on the LER form  
5 to say that if it is a 50.72/73 it's also Part 21? And  
6 I think that's what you're after here, right? Because  
7 I think the examples you cited us in the letter were ones  
8 where yeah, it was 50.72, 50.73 but we didn't check the  
9 Part 21 box. Am I correct in that?

10 MR. PRESCOTT: Well, the - Tom, this is  
11 Paul Prescott from NRO. Yes, for the most part you're  
12 correct, really. That's what it's boiling down to. We  
13 want you to check the other box so the staff is aware  
14 and as you're probably well aware we have an operating  
15 experienced staff. They track our 21s and we've tried  
16 to track LERs but, again, it's been an issue and we're  
17 going to try to hopefully clarify that in your - in your  
18 document with 14-09 to speak more to it. But yeah, it's  
19 a simple nuts and bolts, simple -

20 MR. LOOMIS: It's very simple. You know,  
21 we agree at Exelon. We get the message. We will check  
22 the box. We don't have a problem with that and I get  
23 that question a lot because I own 50.72 for Exelon. I  
24 do lot of consulting on Part 21.

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1           We have no problem with checking the box.  
2           So I just want to get that, you know, clear here and our  
3           guidance document - I'll throw back and put the pitch  
4           in for that -- will have that in there.

5           Well, that guidance document, check the box  
6           and I don't think any of our licensees will have a  
7           problem with checking the box. So, again, it's a simple  
8           -- you know, it is a Part 21 is okay, fine, check the  
9           box. So I think we're in good agreement on that.

10           MR. PRESCOTT: And, again, you know, with  
11           1022 and the current state that it is and after it was  
12           revised you know that there's no guidance related to  
13           Part 21 reporting under there. So we would hope to  
14           catch it under the umbrella of the new guidance to be  
15           developed.

16           MS. HUCKABAY: Thank you. Any other  
17           questions at this time? Okay. Operator, if you have  
18           any questions on the phone we are ready to take those.

19           OPERATOR: Thank you. Sidney Bernsen,  
20           your line is open. Please make sure your line is open  
21           and state your affiliation.

22           MR. BERNSEN: Oh. I'm an independent  
23           consultant. Actually, my comment was on the previous  
24           presentation and not on this one. With regard to

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1 reporting responsibilities, it's my understanding that  
2 the fundamental purpose of Part 21 was to require  
3 suppliers to notify the licensees and the Commission  
4 when a defect was found after they deliver the product.  
5 I don't see the idea of transferring responsibility to  
6 the recipient satisfies the basic intent of Part 21.

7 MS. CLARK: This is - I'm sorry, this is  
8 Lisa Clark and I'm sorry to interrupt you but as we  
9 talked about in the beginning of the meeting today we  
10 are covering a lot of subjects in a short period of time.

11 So I would ask you to hold that question  
12 until we have our general discussion and we're going to  
13 please ask that any comments and questions we take now  
14 are on the subject at hand. Thank you.

15 MR. BERNSEN: All right. The errors of  
16 the operator because I punched in on the previous part  
17 of the presentation. Sorry.

18 OPERATOR: Our next question comes from  
19 either Jessica Hannick or Tracey Zedd. Your line is  
20 open.

21 PARTICIPANT: Yeah. My question had  
22 actually been on the previous section, if that's okay.

23 OPERATOR: Well, this is the operator.  
24 You cut off questions and so - during the previous

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1 section. Are those questions no longer takeable?

2 MS. CLARK: Yes. Let me just clarify. We  
3 are going to ask anybody who had questions on our  
4 previous presentation to hold those questions until we  
5 have our general discussion and so right now we are only  
6 taking questions and comments on the subject at hand.

7 PARTICIPANT: Okay. Then no, I don't have  
8 a question anymore.

9 OPERATOR: Bob Link from Areva, your line  
10 is open. Do you have a question on this current topic?

11 MR. LINK: Yes. I guess it's more of a  
12 question and perhaps a comment. I understand and I  
13 appreciate the characterization on 50.72 and 50.73 or  
14 73.71. But from a fuel cycle facility perspective why  
15 aren't 70.50(h) to Appendix A and 71.95 also included  
16 in a like manner?

17 MS. ATACK: Bob, this is Sabrina Atack.  
18 The reason that 50.72/73 is discussed separately is  
19 because there are specific provisions for reactor  
20 licensees related to their licensee event reports.

21 There are general provisions that are  
22 applicable to all licensees such that if the Commission  
23 is aware that they've already been - you know, they've  
24 already been notified in writing that a defect or

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1 failure to comply exists as part of existing regulatory  
2 requirements for licensees. A duplicate report does  
3 not need to be made.

4 So Part 70 licensees are covered. They're  
5 just not covered under those 50.72/73 specific  
6 provisions because the general provisions in the rule  
7 already cover you if you've already reported under a  
8 different regulatory requirement and that will be the  
9 similar issue where if you're making a separate report  
10 we would want you to identify that this is also a Part  
11 21 issue. Does that address your question, Bob?

12 MR. LINK: I'm not sure because when I read  
13 the words and your deletions and the proposed rulemaking  
14 words yet you still call out 50.72 and 73 explicitly.  
15 So it causes me some confusion because there is no  
16 statement relative to whether a, for instance, an  
17 Appendix A report would satisfy and I agree with your  
18 comment that we must - our obligation as the licensee  
19 must identify that it also is a Part 21 and include the  
20 additional data and information that Part 21 as well as  
21 Appendix A would require.

22 MS. ATACK: I'm pulling up the words right  
23 now so hopefully I can give you that reference real  
24 quick, Bob.

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1 MR. LINK: Well, we can do that offline.  
2 That's fine.

3 MS. ATACK: Okay. Yeah. For -

4 MR. LINK: I think you've heard the intent  
5 and you've given me the impression that the intent is  
6 met.

7 MS. ATACK: Right. So what I'll do after  
8 we come back from lunch then when we get into the fuel  
9 cycle portion is I'll give you the reference and we'll  
10 follow up on that then so we can keep the presentation  
11 moving.

12 MR. LINK: That would be much appreciated.  
13 Thank you.

14 OPERATOR: Our next question or comment  
15 comes from Ken Heffner of Certrec. Do you have a  
16 question or comment on the current topic?

17 MR. HEFFNER: I do. Tom, the logic for  
18 whether or not this requirement to check the Part 21 box  
19 in a 50.72 or 50.73 report whether it's in rulemaking  
20 or in industry guidance seems counter to what the  
21 staff's position was earlier when they stated that they  
22 couldn't rely on industry guidance to tell people how  
23 to report something. And I say that because NUREG-1022  
24 to repeat from the previous section it does have the Part

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1 21.40 it seems like that verbiage -

2 MS. HUCKABAY: You're cutting off. We  
3 can't quite hear you.

4 MR. HEFFNER: I think we should be making  
5 that NUREG-1022 and to tell folks to check that Part 21  
6 box in addition to the 50.72 or 50.73 and not just the  
7 industry guidance for Part 21.

8 MR. PRESCOTT: Thank you for the comment.  
9 What I'd like to bring to your attention is that in  
10 NUREG-1022 they did have guidance - the Part 21  
11 reporting responsibility but it was incorrect and that  
12 it only covered parts on the shelf and that was the only  
13 guidance he gave.

14 It was one single paragraph and that's all  
15 the guidance that was contained in 1022. So due to the  
16 - due to those issues and other issues associated with  
17 the - with the different considerations that go along  
18 with Part 21 reporting responsibilities we think it's  
19 best that the guidance be moved out of 1022 and into its  
20 own guidance document.

21 MR. HEFFNER: Thank you.

22 MR. PRESCOTT: Yup.

23 OPERATOR: No further questions or  
24 comments from the phone.

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1 MS. HUCKABAY: All right. Thank you.

2 Well, we will move on to the next section  
3 here and I am on Slide 52, Section 11 division of Part  
4 21 and 10 CFR 50.55(e) requirements.

5 On Slide 53, we have a description of the  
6 existing regulatory framework. The staff has noted  
7 that Part 21 and 10 CFR 50.55(e) provide nearly  
8 identical regulatory requirements for reporting  
9 defects and failures to comply that would constitute a  
10 substantial safety hazard.

11 Both regulations establish the  
12 requirements for implementing Section 206,  
13 noncompliance of the Energy Reorganization Act of 1974,  
14 and Slide 54 - the similar reporting purposes of Part  
15 21 and 10 CFR 50.55(e) are only distinguished by the  
16 responsible entity and two additional requirements that  
17 are contained in 10 CFR 50.55(e).

18 So the differences between the responsible  
19 entity are here shown on the slide. 50.55(e) applies  
20 to holders of construction permits, combined license  
21 until 10 CFR 52.103(g) finding and manufacturing  
22 license. Two additional requirements in 50.55(e) is  
23 that it requires reporting of any significant breakdown  
24 in any portion of the quality assurance program and

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1 continuing on Slide 55 10 CFR 50.55(e) provides longer  
2 retention requirements for suppliers of basic  
3 components such as ten years for notification to  
4 affected licensees or purchasers versus five years in  
5 Part 21 and 15 years for workers of facilities or  
6 purchasers where basic components were delivered versus  
7 ten years in Part 21.

8 Looking at the regulatory - I'm on Slide 56  
9 - due to the subdivision of requirements being nearly  
10 identical in Part 21 and 10 CFR 50.55(e) this has led  
11 to misinterpretation of the regulatory requirements in  
12 proper implementation by affected parties.

13 Requirements in 10 CFR 50.55(e) are largely  
14 the same as Part 21. The two regulations currently  
15 differ only in terms of the entities to whom the  
16 requirements are imposed on, the length of record  
17 detention and reporting of significant breakdown in the  
18 QA program.

19 This existence of two nearly identical  
20 regulations has led to confusion as to which regulation  
21 is applicable and the staff has noted that combined  
22 license applicants, licensees and their vendors have  
23 been challenged by the applicability of 10 CFR 50.55(e).

24 On Slide 57 we're describing those changes

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1 to the regulations. The staff was considering removal  
2 of 10 CFR 50.55(e) and the corresponding definitions in  
3 10 CFR 50.2 and the adoption of analogous requirements  
4 in Part 21.

5 The staff believes that the regulatory  
6 approach of treating the requirements of 10 CFR 50.55(e)  
7 as a license condition does not adversely affect the  
8 NRC's regulatory capability to ensure compliance with  
9 the substantive requirements.

10 We further propose to delete the  
11 requirement to evaluate a significant QA program  
12 breakdown. We find that this will not further reduce  
13 any regulatory requirements as an indication of a  
14 non-functioning QA program can be related to latter  
15 adequacy in the item of service that was provided.

16 And any questions regarding this section at  
17 this time? We will first take some questions from the  
18 audience here.

19 MR. WILLIS: Yes, this is Fred Willis with  
20 Southern Nuclear. We agree with the staff's  
21 recommendations and we ask that maybe you consider that  
22 you can move forward with the 50.55(e) removal as it is  
23 a separate rule and also since construction is scoped  
24 by 21.2 already.

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1 MS. HUCKABAY: Thank you.

2 MR. CASTELL: Curt Castell, Chicago Bridge  
3 & Iron. In the reg basis we have one where you talk  
4 about the deletion of 50.55(e). You did say that you  
5 would add guidance on how to perform QA breakdown  
6 evaluations into potential guidance that you're  
7 developing. Does that mean that you would require  
8 persons perform an evaluation under Part 21 to do the  
9 QA breakdown evaluation or how was - how was that  
10 intended?

11 MR. PRESCOTT: That last part of your  
12 question, Curt, can you repeat it again? I'm sorry.

13 MR. CASTELL: Do you intend that QA  
14 breakdown evaluations will be conducted by all persons  
15 and parties that are required to comply with Part 21?

16 MR. PRESCOTT: Actually, that's an  
17 interesting question, Curt. I'll have to take it back.  
18 The original - as you know, the original historical  
19 perspective behind that was - that it was during the  
20 original construction days, you know, the issues where  
21 a lot of new people enter the business.

22 I think the goal was or thought was that  
23 there are still a lot of new people coming in so  
24 potentially they would have to evaluate. But the staff

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1 will take that back for consideration of the exact  
2 interpretation.

3 MR. CASTELL: Okay. Thank you.

4 MR. PRESCOTT: Thank you.

5 MS. HUCKABAY: Thank you.

6 MR. HEATH: Just to clarify, yes. I mean,  
7 what we're - what we're proposing thus far is to remove  
8 that evaluation requirement for 50.55(e) altogether and  
9 just move that into guidance space. But that - if it's  
10 in guidance space there is no requirement to perform  
11 that evaluation under the regulation.

12 MR. SALTER: This is Findlay Salter from  
13 South Carolina Electric & Gas. I'd just like to  
14 reiterate the industry's support to remove the  
15 requirement to evaluate and report significant  
16 breakdowns in the quality assurance program.

17 We agree with the staff that there's no  
18 reduction in regulatory requirements with the resources  
19 exerted on our end to evaluate and report those  
20 conditions. So thank you.

21 MS. HUCKABAY: Thank you. It looks like  
22 we don't have any further questions from the audience  
23 here. Operator, do you have anybody on the phone?

24 OPERATOR: No questions or comments on the

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1 phone, no. Wait - one - we have a follow-up question  
2 or comment from Sidney Bernsen. Your line is open.

3 MR. BERNSEN: Yes. Under subject - I'm  
4 going to have to write a discussion because obviously  
5 the industry and the regulator don't have a full  
6 understanding of the original intent of 50.55(e) and the  
7 difference between that and Part 21 and also the  
8 reporting during operations.

9 I won't discuss it now but I will send you  
10 a comment on that because I think that program  
11 breakdowns are significant during the construction  
12 phase and something that needs to be alerted to the  
13 Commission. End of comment.

14 MS. HUCKABAY: Thank you.

15 OPERATOR: No further questions or  
16 comments from the phone.

17 MS. HUCKABAY: All right. I guess Paul  
18 Prescott will take it from here.

19 MR. PRESCOTT: There's a note up here that  
20 says speak more slowly. Well, I hope you've taken your  
21 Evelyn Wood speed reading course because in the interest  
22 of time and, really, what we're here for is to get  
23 feedback from you guys. I'm going to move this along  
24 at a fairly good clip, okay?

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1                   So Slide 59 - we're going to talk about  
2                   Section B, proper place for a commercial-grade  
3                   dedication requirements. All right. Let's go to  
4                   Slide 60.

5                   Well, essentially, as you know dedication  
6                   has evolved since the early days when it was first seen  
7                   for simple metallic objects to us dedicated or the  
8                   industry dedicating everything from software to  
9                   emergency gas turbine diesel - gas turbine generators.  
10                  So it's gotten a lot bigger, and one of the ways we've  
11                  handled that is we've worked with the industry and I want  
12                  to throw a thank you out there to the industry for the  
13                  work that's been accomplished to achieve the document  
14                  that we have on commercial-grade dedication. I look  
15                  forward to reviewing that and getting it approved on a  
16                  short amount of time.

17                  Slide 61 - again, the idea here is that  
18                  dedication should not reside in a definition. It's not  
19                  the appropriate place for it. It's not a - it is  
20                  strictly a definition and what is dedication but a  
21                  process and here we're trying to stress the process of  
22                  dedication, to ease out what we see as ways of  
23                  accomplishing that and separating what dedication is in  
24                  its own Part 21.71, which will be a new section.

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1                   Why do we think there's a need for it?  
2                   Well, again, we go back to the historical problems that  
3                   we've seen with dedication and the way it's been carried  
4                   out. Yes, I agree guidance will take care of a lot of  
5                   that. But part of the issue has been that we're looking  
6                   to have the words match the guidance, which hasn't been  
7                   what's - the way it has been in the past.

8                   So what are we proposing to do?  
9                   Essentially, we'll stress about the documentation  
10                  phase, stressing that you perform a technical  
11                  evaluation. Why?

12                  Because of generic letter stress  
13                  engineering involvement in dedication and that's what  
14                  we want to see through the technical evaluation and  
15                  we're going to clearly delineate the acceptance methods  
16                  and finally we're going to maintain the bare essentials  
17                  of the dedication process to provide strong regulatory  
18                  framework for the dedication process.

19                  I'm missing a few slides but that's good,  
20                  actually. The way it works. Okay. So if there's any  
21                  questions I'd be more than happy to take them at this  
22                  point related to this subject.

23                  All right. Oh, I'm sorry. Operator, are  
24                  there any questions from the people online?

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1 OPERATOR: Please stand by. There is a  
2 question forthcoming. It will be from Bob Link of Areva  
3 as soon as it arrives. Mr. Link, your line is open.

4 MR. LINK: I guess my question is regarding  
5 the wording in the proposed 21.71 on Page 113 of the reg  
6 basis document where in a - I'll admit this is - it's  
7 all in the eyes of the reviewer or reader where it in  
8 worst case would back fit a Part 70 licensee to have an  
9 Appendix B program.

10 Specifically, the words are in fuel  
11 fabrication facilities licensed under 10 CFR Part 70  
12 dedication ensures that a commercial-grade item is  
13 controlled under a quality insurance program complying  
14 with Appendix B to Part 50 of this chapter.

15 MS. ATACK: Hi, Bob. It's Sabrina Atack.  
16 I'll address your comment. It's actually just a little  
17 bit of - yeah, it's in the eye of the reader, as you said.

18 You have to read that excerpt such that you  
19 include the plutonium processing in fuel fabrication  
20 plans as one phrase and that's consistent with the  
21 wording in Part 70. So it's not all fuel fabrication  
22 plans licensed under Part 70. It's only those that  
23 process plutonium.

24 MR. LINK: Okay. Well, I guess I would

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1 just try to get that crystal clear.

2 MS. ATACK: Okay. I'll take that under  
3 advisement. Thank you.

4 OPERATOR: No further questions or  
5 comments from the queue.

6 MR. PRESCOTT: Okay. I'm going to jump to  
7 Slide 70 - Number 70, for those online.

8 Okay, spoiler alert. Here's the new  
9 definition of dedication that staff is proposing -  
10 short, sweet and truly to the point and now qualifies,  
11 to my mind at least, as a definition.

12 Next slide, 71 - as discussed earlier, the  
13 dedication cookbook has been removed. There is no  
14 discussion on who, by whom and how dedication is  
15 performed. It is - it is all addressed in the initial  
16 21.71 chapter that opens up the new paragraph in the  
17 proposed rulemaking.

18 Okay. Why did we do this?  
19 Straightforward, to clarify the concept of dedication  
20 and that it's a process, and as I stated before the staff  
21 does not believe that the definitions are the proper  
22 methodology for trying to perform dedication. And we  
23 think this makes it clearer not just for licensees but  
24 we took into account sub-tier, dedicating entities and

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1 top-tier vendors.

2 Slide 73 - and so one of the points that I'd  
3 like to make with this is that - Slide 69. I love my  
4 life. Okay. One of the points - okay. One of the  
5 points I'd like to make with this is that the changes  
6 dovetail with the new guidance and we feel that aligning  
7 the latest industry guidance would be - with the  
8 regulation is the appropriate thing to do. So with  
9 that, I'll take your questions. No? Okay.

10 MR. NICHOL: Paul, Marc Nichol from NEI.  
11 So I'll just make a general comment. I think it'll be  
12 the same for a lot of these sections on commercial-grade  
13 dedication.

14 I think that the clarifications they are  
15 reflected in EPRI's guidance on commercial-grade  
16 dedication. That guidance is consistent with the  
17 existing rule language.

18 So to that effect, we believe that in the  
19 area of commercial-grade dedication the rules have not  
20 prevented anything - that the issues that have been  
21 experienced are due to clarity issues reflected in a  
22 lack of comprehensive guidance that was endorsed by the  
23 NRC. So we think the effective approach is just to  
24 endorse EPRI guidance.

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1 OPERATOR: Star one to ask a question.  
2 Currently no questions in the queue.

3 MR. PRESCOTT: Okay. Go to Slide 73.  
4 Okay. So what was identified with the problem of the  
5 definition of dedicating entity? Well, to me this is  
6 America. Everybody should be able to dedicate and that  
7 was the idea behind this change.

8 As you know, there was a lot of baggage  
9 associated with the previous definition and ability to  
10 -- especially on Type 70 licensees, and so the idea here  
11 was to try and capture that. I clarify what that is in  
12 the presentation.

13 OPERATOR: Apologies. This is the  
14 operator. Your mike has cut out.

15 MR. PRESCOTT: Okay. Go to Slide 74 and,  
16 again, I'm sure Sabrina will address this further but  
17 as I stated earlier the idea here is that we want to be  
18 all inclusive in dedication and the issue was also for  
19 us - from our standpoint was Part 52 licensees were not  
20 captured in the definition of a dedicating entity.

21 So now we're moving it and having the  
22 clarifying statement up front. We'll clarify who can  
23 perform dedications. And, again, I'm sure Sabrina's  
24 going to talk about this some more but since 2008 we've

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1 had a number of license exemptions come in asking how  
2 to do this -

3 MS. CLARK: Oh, I'm sorry.

4 MR. PRESCOTT: - under the current  
5 conditions.

6 MS. CLARK: Operator, can you hear on --

7 OPERATOR: This is the operator. I can  
8 hear you. The gentleman sometimes is audible,  
9 sometimes he fades in and out.

10 MR. PRESCOTT: Again, this is hard for me.  
11 I kind of move around a lot. So I'm going to try to stand  
12 here as still as I possibly can and, really, I've  
13 captured what I wanted to say.

14 The issue with dedicating entity was, you  
15 know, not all parties were shown to be able to dedicate  
16 Part 52 non-reactor facilities and the idea is to  
17 rectify that moving forward with the rulemaking. And  
18 so I'll take questions now if there's any.

19 MS. AUSTGEN: This is Kati Austgen from the  
20 Nuclear Energy Institute. Certainly, we believe that  
21 anyone should be able to dedicate including the Part 52  
22 licensees and I would note that there is a Part 52  
23 lessons learned rulemaking going on right now and one  
24 of its purposes is to take care of the one-offs such as

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1 this and other regulations where Part 52 was  
2 inadvertently admitted from those who were able to use  
3 it.

4 MR. PRESCOTT: Thank you.

5 MR. DUNKELBERGER: Michael Dunkelberger,  
6 MPR. My one question or comment on dedication has to  
7 do with the technical evaluation as it relates to  
8 services and I know someone recently who got written up  
9 because they didn't have a technical evaluation to  
10 support the critical characteristics they had  
11 identified for a calibration service.

12 In my opinion, what's important about  
13 calibration is fairly well understood and would just  
14 hope that the rule change doesn't make it sound like you  
15 need an elaborate evaluation to identify those critical  
16 quality controls with a service such as that.

17 MR. PRESCOTT: Now, that has been  
18 addressed, Mike, by the guidance issued by the NEI. The  
19 number escapes me right now - no, for the ILAC.

20 MR. DUNKELBERGER: Oh, 14-05.

21 MR. PRESCOTT: 14-05 - thank you very much.  
22 Yes, 14-05 provides a level of detail necessary to  
23 perform that evaluation for the calibration of  
24 suppliers. But to reiterate also about other services

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1 that's also now addressed in the revised 5652 on  
2 commercial-grade dedication.

3 MR. DUNKELBERGER: Yeah, I think they got  
4 cited against the new revision to the EPRI 5652  
5 requiring a technical evaluation for calibration  
6 services and I need to dig into that more clearly. But  
7 I -

8 MR. PRESCOTT: Okay.

9 MR. DUNKELBERGER: - it seems like what  
10 they got - you know, in my opinion it wasn't valid.

11 MR. PRESCOTT: Right. Thank you, Mike.

12 MR. LOOMIS: Hi, Paul.

13 MR. PRESCOTT: Hi, Tom.

14 MR. LOOMIS: Tom Loomis from Exelon here.  
15 We noticed on 21.7 on exemptions that there was a  
16 sentence struck from there where it says suppliers of  
17 commercial-grade items are exempt from the provisions  
18 of this part to the extent that they supply  
19 commercial-grade items. Was that intentional you  
20 struck that provision out of there or did you see it as  
21 a duplication? We caught that and we weren't sure what  
22 you were intending by that strikeout.

23 MR. HEATH: Where is that, Tom?

24 MR. LOOMIS: On 21.7 on exemptions on Page

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1 106 in the reg basis.

2 MR. PRESCOTT: I'll go back but I believe  
3 - I believe that strikeout is correct because if you  
4 supply a commercial-grade item - a commercial-grade  
5 item then are going to be a basic component. But we'll  
6 verify that. Thank you, Tom. That's a good point but  
7 -

8 MR. LOOMIS: Yeah. Yeah. And, you know,  
9 here again this is kind of like where our point goes and  
10 I'm going to follow the theme again as we look at that  
11 strikeout and we as an industry if we're trying to gain  
12 clarity we get ourselves into a confusing situation.

13 So that's why we say let us deal with it from  
14 the guidance viewpoint sitting across a table and we'll  
15 work through it so if there was an issue there. But,  
16 you know, again, these strikeouts and so forth are  
17 rearranging.

18 That was a lot of trouble for us and, again,  
19 let me give you a class example as the 50.72, 50.73 -  
20 the recent guidance that came out on that. I know we  
21 worked well with the NRC on that but in the end there  
22 were some changes made to that 50.72 and 50.73 rule that  
23 we weren't really aware of and as a result now we're  
24 having to submit license amendments to correct that

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1 situation.

2 So again, we get into that unintended  
3 consequences situation. That's why we hope that we can  
4 sit and work through the guidance across the table and  
5 hammer that out so we all get what we want out of this.  
6 That's where we want to go on it.

7 MR. HEATH: So to answer your question, the  
8 strikethrough is intentional and is simply - and I think  
9 Paul said it already but I'll just reiterate it, that  
10 suppliers of commercial-grade items the idea is that  
11 they would be exempt because items that they supply are  
12 not basic components. They're not - they're not  
13 dedicated. That's the idea. Thank you.

14 MS. CLARK: Could you please go to the  
15 microphone?

16 MR. LOOMIS: I'll provide - let me just  
17 find that comment because the fact you just take that  
18 out that does remove clarity from the regulation and  
19 that's the type of clarity that we need to be able to  
20 follow through with that and by taking that out that does  
21 create confusion for us.

22 So, again, you know, what is the aim here?  
23 Are we trying to clarify things or are we trying to make  
24 it more difficult for us to comply? So I'll just follow

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1 you.

2 MS. HUCKABAY: And if I could just add one  
3 more thing. So we understand these comments and will  
4 certainly take it under consideration and the - just to  
5 mention once again that the proposed draft rule language  
6 in Appendices A and B is just for illustration purposes  
7 only. This is not something that our Office of General  
8 Counsel has approved. So this is - this is certainly  
9 very preliminary and, you know, we'll need more most  
10 certainly.

11 MR. PRESCOTT: Other questions related to  
12 that section? Operator, on the phone is there any  
13 questions related to this section?

14 OPERATOR: Two questions. First  
15 question, Charles Slama, I believe, of Urenco. Your  
16 line is open.

17 MR. SLAMA: Yes, this is Charles Slama,  
18 Urenco - that's correct. This is - this 21.7 exemption  
19 definition - Sabrina, this is something I believe I've  
20 spoken with you in the past about.

21 When I look at that definition - suppliers  
22 of commercial-grade items are exempt - the reason that  
23 that statement is important to leave in there is because  
24 bottom line it's absolutely true.

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1                   When we look at bringing commercial-grade  
2 items on site and making them a basic component, what  
3 I'm looking for in terms of Part 21 and making something,  
4 a basic component, the quality aspects apply to that.  
5 Those quality aspects are the commercial-grade  
6 dedication process that I perform whether it's an  
7 on-site engineering analysis or it's testing and  
8 analysis done offsite with some QL1 - in our case some  
9 QL1 test lab.

10                   So I think it is important to provide some  
11 clarification that what is - what is subject to this part  
12 is the quality process that makes that item a  
13 commercial-grade item or make that commercial-grade  
14 item a basic component, hence the reason why the  
15 commercial-grade supplier who may be Joe's Hardware  
16 Store down the street it's completely exempt from Part  
17 21 if they have no part of making that thing a basic  
18 component. That's all I have.

19                   MS. ATACK: Thanks, Chuck, and I think  
20 we'll look at that as we look at, you know, clarifying  
21 the rule and the guidance. But I think the initial intent  
22 was to - just to remove duplication. You know,  
23 obviously, if it's a commercial-grade item you're not  
24 subject to the evaluation and reporting requirements

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1 because it's a commercial-grade item and it's not yet  
2 - it hasn't been dedicated and such that it's subject  
3 to evaluating and reporting.

4 But if we need that level of clarity, you  
5 know, I think that's something the staff can definitely  
6 look at. And, you know, I think that we did try to  
7 provide clarification to describe that the dedication  
8 process is subject to certain, you know, quality  
9 assurance controls.

10 So in that area we tried to clarify it as  
11 really that dedication process that gets you into the  
12 quality assurance, you know, to that role and then once  
13 the item is dedicated as a basic component then you're  
14 subject to evaluating and reporting. But if we haven't  
15 met the mark in providing that level of clarity I think  
16 we'll definitely look into improving that.

17 MR. SLAMA: Okay. Thank you.

18 OPERATOR: Bob Link from Areva, your line  
19 is open.

20 MR. LINK: Yeah, I was - thank you. Ditto.  
21 I guess the - I'll just add that the - I believe the  
22 remaining words in 21.7 could lead the reader to say that  
23 suppliers of commercial-grade may be or even are subject  
24 to this part. So think the sentence remaining in there

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1 is very important for that clarity.

2 MR. HEATH: Okay. I mean, I think what the  
3 staff envisioned is that the strikethrough is there  
4 simply because the statement was under - ought to be  
5 understood by the other definition in the current  
6 regulations.

7 But, again, as Victoria pointed out, don't  
8 focus or key in on the rule language that you see in the  
9 back of the appendices. Again, it's just kind of an  
10 illustration on what the staff was thinking.

11 None of this has been vetted and we're not  
12 even sure if this is what the proposed rule is going to  
13 look like. But, again, we're taking your comments -  
14 we'll take that into consideration to make sure we're  
15 doing the right thing on that. Thank you.

16 OPERATOR: No further questions or  
17 comments from the phone.

18 MS. HUCKABAY: Okay. This is Victoria  
19 Huckabay again and we're going to move on to Section E,  
20 Definition of Commercial-Grade Item, and I am now on  
21 Slide Number 78.

22 So first, we're going to talk about the  
23 existing regulatory framework. Part 21, as we have  
24 just discussed, distinguishes a commercial-grade item

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1 from a basic component.

2 For power reactors, a commercial-grade  
3 item is currently defined in 10 CFR 21.3 as follows:  
4 When applied to a nuclear power plant's license pursuant  
5 to 10 CFR Part 50, commercial-grade item means the  
6 structure, system or component or part thereof that  
7 affects the safety function that was not designed and  
8 manufactured as a basic component.

9 Commercial-grade items do not include  
10 items where the design and manufacturing process  
11 require in-process inspections and verifications to  
12 ensure the defects or failure to comply are identified  
13 and corrected, such as one or more critical  
14 characteristics of the item cannot be verified.

15 The purpose of distinguishing a  
16 commercial-grade item from basic components for power  
17 reactors as well as non-power reactors and non-reactor  
18 facilities and licensees - excuse me, facilities and  
19 activities was to clarify - clearly specify the  
20 characteristics of a commercial-grade item which are  
21 not subject to the reporting requirements of Part 21.

22 Next slide, Slide Number 79 - the  
23 regulatory issue that the NRC has identified is that the  
24 current definition for power reactor licensees has been

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1           incorrectly interpreted by industry to mean that the  
2           specific     design     or     manufacturing     critical  
3           characteristic can only be verified through an  
4           in-process inspection.

5                     Inspections, in fact, are just one  
6           verification method available under the dedication  
7           process. A commercial-grade item may still be capable  
8           of being dedicated by verifying in-process design and  
9           manufacturing     critical     characteristics     through  
10          testing.

11                    And, again, just to remind you from the  
12          definition of dedication in 10 CFR 21.3 it states that  
13          the assurance can be achieved by identifying critical  
14          characteristics of the item and verifying their  
15          acceptability by inspections, tests or analyses  
16          performed by the purchaser or third party dedicating  
17          entity after delivery and then further supplemented as  
18          necessary by commercial-grade surveys, product  
19          inspections or witness at hold points at a  
20          manufacturer's facility and analysis of historical  
21          records.

22                    Slide Number 80 - proposed changes to the  
23          regulations - the staff is proposing to revise the  
24          definition of commercial-grade item to clarify that it

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1 is simply an item that is not a basic component. With  
2 this definition the dedication process in the new  
3 proposed Section 10 CFR 21.71 would appropriately  
4 determine if the commercial-grade item could be  
5 dedicated and therefore designated as a basic  
6 component.

7 In addition, the staff is considering  
8 making the definition of a commercial-grade item  
9 equivalent for reactor and non-reactor facilities.  
10 Under this proposal, all items not designed and  
11 manufactured under an appropriate QA program would be  
12 considered commercial-grade items.

13 One of those requirements that would be  
14 maintained in the dedication process description would  
15 prohibit dedication if any critical characteristic of  
16 the item cannot be verified as acceptable.

17 And we'll take any questions at this time  
18 with regard to this section, and just a quick note -  
19 again, we will discuss this issue as it pertains to  
20 non-power reactors and non - I'm sorry, non-reactor  
21 facilities in a later session this afternoon. But if  
22 you have a question about the reactor facilities we can  
23 take that right now. Marc?

24 MR. NICHOL: Marc Nichol, NEI. Just a

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1 clarifying question on Page 80. So the last bullet is  
2 dedication would be prohibitive if any critical  
3 characteristic cannot be verified as acceptable.

4 Does this mean directly verified or does  
5 this also include indirectly verified? For example,  
6 some critical characteristics could only be verified by  
7 destructive testing and so that wouldn't be really a  
8 means to verify the critical characteristics. So would  
9 some other equivalent indirect verification be  
10 acceptable?

11 MR. PRESCOTT: Yes. Yes.

12 MR. NICHOL: Okay. Okay.

13 MR. PRESCOTT: That would be the intent and  
14 the guidance covers that. But, you know, the point was,  
15 as you know, the old definition talked about, you know,  
16 that it had to be - it was during the manufacturing  
17 process and you may not be able to - then you can't verify  
18 the critical characteristic.

19 Well, it could be argued that there's  
20 methods available through dedication that I could  
21 verify something that's in a hermetically sealed relay,  
22 for instance, right? Let's just say this spring,  
23 right. Normally, it called for the spring - normally  
24 it called for the spring to somehow be verified what that

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1 material is.

2           Okay, one method is to destructively test  
3 it but I would argue that a clever engineer could come  
4 up with a methodology that shows if I exercise the spring  
5 100 times and it comes back within these property ranges  
6 then I've verified what the property of that material  
7 of the spring that was called out for is. So, again,  
8 it's to - I don't want to stifle the creativity of  
9 dedication. That's what I'm trying to call out here and  
10 get rid of the old definition.

11           MS. HUCKABAY: And the- looks like we don't  
12 have any other questions from the audience right now.  
13 Operator, do you have any questions on the phone?

14           OPERATOR: Yes. We have three questions.  
15 First, Mike Leahy from Exelon. Your line is open.

16           MR. LEAHY: Yes. This is Mike Leahy from  
17 Exelon. My question is in the current ruling the  
18 definition includes the concept of reasonable assurance  
19 that the process is to achieve reasonable assurance.

20           In the proposed regulation where you move  
21 the information from the definition to the new Section  
22 21.71 I didn't see in there any discussion about  
23 reasonable assurance.

24           It seemed to be absolute terms - all

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1 critical characteristic must be identified, all must be  
2 demonstrated. And so that's really my question.

3 I would expect the concept of reasonable  
4 assurance is intended be essential to the 21.71. Is  
5 that correct?

6 MR. PRESCOTT: This is Paul Prescott, NRO.  
7 It's in alignment with - still with, we expect,  
8 reasonable assurance. But we've always - the staff's  
9 position has been if it is a critical characteristic  
10 that you've identified that has to be verified, it has  
11 to be verified.

12 We've held that position for as long as I  
13 know. And the - we still believe in reasonable  
14 assurance. Again, this goes back to the concept of, you  
15 know, whatever it is that you've determined is necessary  
16 or reasonable to show then you verify it. In the guidance  
17 - the new guidance related to 5652 reflects that same  
18 thought process.

19 MR. LEAHY: Okay. That's what I was  
20 hoping you would say. So my only request would be to  
21 consider maybe adding the terms reasonable assurance  
22 into the 21.71 discussion.

23 MR. PRESCOTT: And we've made a note of  
24 that. Thank you. We will take a look at that.

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1 MR. HEATH: I'm not sure we intended to  
2 omit that in the rule.

3 OPERATOR: If no further comment from Mr.  
4 Leahy?

5 MR. LEAHY: Yeah, I'm done. Thank you.

6 OPERATOR: I have Bob Link from Areva.

7 MR. LINK: I believe it's been asked and  
8 answered but just to reinforce it again, especially with  
9 fuel cycle facilities, the ability to verify and  
10 whatever that word means all critical characteristics.  
11 Many times we'll buy a catalog item and the catalog item  
12 it says it's got a stainless steel, you know, body and  
13 the only way to verify it, in my mind, would be to do  
14 destructive testing or analyzing the body itself.

15 Well, yet if we evaluate the receipt of the  
16 item and the receipt part number matches and the part  
17 numbers says it's supposed to have a, you know, a certain  
18 stainless steel alloy body that's reasonable  
19 verification, in my opinion.

20 MS. HUCKABAY: Thank you for your comment.  
21 We will have a discussion on this subject later this  
22 afternoon during the fuel cycle facility session. But  
23 thank you for your comment. We will make a note of it.

24 OPERATOR: Last question or comment -

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1 Sidney Bernsen, independent consultant. Your line is  
2 open.

3 MR. BERNSEN: Yes. I think it really is  
4 similar to the previous observation, which really isn't  
5 for fuel cycle as well. But there are a lot of  
6 commercial items out of catalogs that are incorporated  
7 in basic components and these things can't be verified  
8 other than through quality, history and the  
9 manufacturer's product description.

10 I think that - I just don't understand how  
11 you can exclude all of these commercial little pieces  
12 that go into all the safety related items and say that  
13 you have to verify their critical characteristics  
14 other than through experience with the manufacturer and  
15 the quality of their products.

16 MR. PRESCOTT: The current - the current  
17 guidance - this is Paul Prescott, NRO - the current  
18 guidance is spelled out in 5652 and it goes along the  
19 lines just like generic letter 89-02 spelled out that  
20 you can't take credit alone for historical performance.  
21 It has to be backed up by something else, whatever that  
22 something else may be - one of the other three methods,  
23 obviously. But at the current state of us for reactor  
24 facilities, that's what it is.

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1 MR. HEATH: The position has always been  
2 that the --

3 OPERATOR: No further comments in the  
4 queue, just to add if your question has been asked and  
5 answered on the phone you can press start two to exit  
6 the queue again. No further questions.

7 MS. HUCKABAY: All right. Thank you. We  
8 are going to move on to a discussion - I'm sorry,  
9 discussing Section F, Basic Component as Equivalent to  
10 Safety-Related for Facility Subject Appendix B, and I  
11 am on Slide 83.

12 The definitions of a basic component are  
13 provided in 10 CFR 21.3 and safety related in 10 CFR  
14 50.2, which are intended to refer to the same set of  
15 structures, systems and components vary slightly.

16 The basic component as it applies to power  
17 reactor facilities is defined in 10 CFR 21.3 as follows:  
18 When applied to nuclear power plants licensed under 10  
19 CFR Part 50 or Part 52 of this chapter, basic component  
20 means a structure, system or component or part thereof  
21 that affects its safety function necessary to assure the  
22 integrity of the reactor coolant pressure boundary, the  
23 capability to shut down the reactor and maintain it in  
24 a safe shut down condition or the capability to prevent

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1 or mitigate the consequences of accidents which could  
2 result in potential offsite exposures comparable to  
3 those referred to in Sections 50.34 (a) (1), 56.27(b) (2)  
4 or 100.11 of this chapter is applicable.

5 And on Slide 84 we have the definition of  
6 safety-related systems, structures or components for  
7 reactor facilities, which are defined as those  
8 structures, systems or components that are relied upon  
9 to remain functional during and following design basis  
10 events to assure the integrity of the reactor coolant  
11 pressure boundary, the capability to shut down the  
12 reactor and maintain it in a safe shut down condition  
13 or the capability to prevent or mitigate the  
14 consequences of accidents, which could result in  
15 potential offsite exposures comparable to the  
16 applicable guideline exposures set forth in 50.34 (a) (1)  
17 or 100.11 of this chapter.

18 So the regulatory issue on Slide 85 is that  
19 the definitions for a basic component and safety related  
20 do not align. Specifically, the use of the terms  
21 "affects its safety function" in the definition of basic  
22 components.

23 It is less specific than that provided in  
24 the definition of safety related, as you just saw, and

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1 this has led to inadequate application of QA controls  
2 to basic components by vendors and licensees.

3 On Slide 86, proposed changes to the  
4 regulations, the staff is considering revising the  
5 definition of basic component to align with definition  
6 of safety related. In the preliminary draft rule  
7 language this new definition would more closely match  
8 that of safety related as currently defined in 10 CFR  
9 50.2 without changing its meaning.

10 The NRC staff does not intend to  
11 differentiate between basic component and safety  
12 related or apply separate criteria for determining  
13 which structures, systems, and components are basic  
14 components or safety related.

15 And if you have any questions the members  
16 of the public in attendance please ask them at this time.  
17 Looks like we don't have any questions here. Operator,  
18 do you have any questions on the phone?

19 OPERATOR: No questions from the phone.  
20 As always, star one to ask a question.

21 MS. HUCKABAY: Okay. Then we are going to  
22 move forward and Section G, QA requirements for the  
23 conduct of the dedication for facility subject to  
24 Appendix B.

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1                   Here on Slide 89, the existing regulatory  
2                   framework, 10 CFR 21.3 includes the definition for  
3                   dedication as applied to power reactor licensees and  
4                   includes the following substantive requirement which  
5                   states that in all cases the dedication process must be  
6                   conducted in accordance with the applicable provisions  
7                   of 10 CFR Part 50 Appendix B.

8                   There are no similar statements to identify  
9                   the QA requirements applicable to dedication activities  
10                  for other facilities subject to the requirements of Part  
11                  21.

12                  I'm on Slide 90. The regulatory issue  
13                  identified by the staff is the regulatory framework for  
14                  dedication which includes the application of necessary  
15                  QA controls resides primarily in the definition of  
16                  dedication found in 10 CFR 21.3.

17                  It is our long-standing position that  
18                  substantive regulatory requirements should not reside  
19                  solely in definitions.

20                  NRC inspectors have found during their  
21                  inspections of power reactor licensees that many  
22                  dedication activities are performed improperly without  
23                  being in accordance with applicable provisions of  
24                  Appendix B.

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1           A common example provided in the draft reg  
2 basis is that dedication is performed without adequate  
3 documentation as required by Criterion V,  
4 "Instructions, Procedures, and Drawings" of Appendix B.

5           Slide 91, proposed changes to the  
6 regulations, the staff is considering adding an express  
7 requirement as part of new Section 10 CFR 21.71 on  
8 commercial-grade dedication that identifies that  
9 dedication must be conducted in accordance with  
10 Appendix B for those entities subject to the  
11 requirements of Appendix B.

12           We find that this will provide clear  
13 regulatory infrastructure to communicate dedication  
14 requirements. For reactor licensees, moving the  
15 requirement from the definition of dedication to a new  
16 section on dedication will support a better  
17 understanding of the requirements since they will all  
18 be contained in one consolidated section.

19           Are there any questions regarding this  
20 subject at this time from the audience, please?

21           Hearing none, are there any questions on  
22 the phone?

23           OPERATOR: Yes, we have one question from  
24 Adam McCartney, if you can identify your affiliation.

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1 Your line is open.

2 MR. MCCARTNEY: Yes, Adam McCartney with  
3 Cameron. I'm kind of confused with the statement of -  
4 at a requirement in the new section on commercial-grade  
5 dedication 10 CFR 21.71 that identifies dedication must  
6 be conducted in accordance with Appendix B.

7 There is nothing in Appendix B that  
8 describes dedication. So how can it be done in  
9 accordance with Appendix B?

10 MS. HUCKABAY: Well, I think - so if I can  
11 refer you to - back to - let me just - if we go back to  
12 Slide 89, looking at the existing regulatory framework,  
13 so for power reactors the existing regulatory framework  
14 what we have in 10 CFR 21.3 currently states that in all  
15 cases the dedication process must be conducted in  
16 accordance with the applicable provisions of 10 CFR Part  
17 50 Appendix B. That's already in the regulations.

18 So what you're proposing actually is not -  
19 is not new. We find that there is an issue with having  
20 the statement buried in the definitions and we find that  
21 the - it would be - it would be beneficial in a more  
22 clearly communicated requirement in our regulations to  
23 essentially move that, if you will. And perhaps  
24 somewhat rephrase that exact statement in the new

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1 Section 21.71. Does that answer your question?

2 MR. MCCARTNEY: Well, I'm not sure because  
3 I understand that the current framework could be flawed  
4 because if we're executing our Appendix B programs the  
5 way they were intended theoretically we don't need  
6 dedication.

7 MR. PRESCOTT: And to the question of  
8 implementation and as a matter of fact we discuss that  
9 quite a bit in the new guidance.

10 But if you're - if you're controlling  
11 something under your Appendix B program then you're not  
12 dedicating, if that's what you're doing.

13 But if you - but if you're taking a  
14 commercial item and making it a basic component and you  
15 need to verify certain things then you're in the  
16 dedication process.

17 So something either becomes a basic  
18 component by implementation of the Appendix B program  
19 or a dedication program, and to be a dedicating entity  
20 you have to have the Appendix B program. Why? Because  
21 we expect dedication to be formed under the auspices of  
22 an Appendix B program.

23 MR. MCCARTNEY: Yes, I agree.

24 MR. PRESCOTT: Okay.

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1 MR. MCCARTNEY: It's just a little bit - it  
2 was a little bit confusing in that you're expecting  
3 dedication to occur in accordance with Appendix B and  
4 really you need to have an Appendix B program to perform  
5 dedication, which are separate.

6 MR. PRESCOTT: Thank you, yes.

7 MS. HUCKABAY: Yes, thank you.

8 OPERATOR: Next up is Sidney Bernsen,  
9 independent consultant. Your line is open.

10 MR. BERNSEN: Yes. It seems like Appendix  
11 B is going to need to be modified to accommodate what  
12 the staff has done in Part 21 because if you read  
13 Appendix B it doesn't necessarily apply to anybody but  
14 applicants - essentially, licensees, permit holders -  
15 and it says they may delegate parts of it to others but  
16 it doesn't put requirements on all of the supply chain.

17 It only puts requirements on the applicant  
18 and therefore it's awfully difficult for one to  
19 understand how a manufacturer has needed an Appendix B  
20 program. Also, is the boiler code invoked in Appendix  
21 B? Because certainly a lot of components are built  
22 under the ASME Section III boiler code. So somebody  
23 needs to look at Appendix B in order to make it  
24 applicable to the way that the staff has been enforcing

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1 it for the last 20 years.

2 MR. PRESCOTT: Now, I don't - this is Paul  
3 Prescott. I don't think so, Sid. Essentially, it's  
4 been passed down through the procurement documents.  
5 It's been contractually imposed on the - by the  
6 licensees and that's how it's passed down.

7 MR. BERNSEN: I understand that but the  
8 licensees - I don't know what they pass down because I  
9 don't know what's applicable to each of their suppliers.

10 Anyway, that's a separate discussion. All  
11 I'm saying is that the words in Appendix B if a lawyer  
12 interprets them don't fit your applications.

13 MR. PRESCOTT: Okay. Thank you.

14 OPERATOR: No further questions or  
15 comments in the queue.

16 MS. HUCKABAY: Okay. Thank you.

17 MS. CLARK: I think this is a good time to  
18 break for lunch. We will reconvene at 1:00 o'clock.

19

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

2 (1:01 p.m.)

3 MS. CLARK: Good afternoon and welcome  
4 back. We are resuming our public meeting to discuss  
5 Part 21.

6 And just a couple of reminders. If anybody  
7 is new this afternoon there are sign in sheets at the  
8 very back of the room, so please be sure to sign in.

9 And I hope you had a good lunch. Please  
10 remember to silence any telephones or any other  
11 electronic devices.

12 We are going to start with the presentation  
13 on the administrative changes. And following that  
14 we're going to have our open discussion so that people  
15 will have an opportunity to present any additional  
16 questions or comments regarding our discussion this  
17 morning. We very much appreciate you holding those  
18 questions.

19 And we want to give you a full opportunity  
20 to present all of our views on that. And we'll focus  
21 on that very shortly. Thanks.

22 MS. HUCKABAY: Thank you. This is  
23 Victoria Huckabay again. So just a quick note before  
24 we discuss administrative changes here.

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1           Sorry about that, we have our slides in  
2 slightly different order. I need to get to my section  
3 here real quick. All right.

4           Just a quick note. Something that we  
5 perhaps did not mention earlier this morning, for  
6 members of the public attending here today in person,  
7 emergency. In case of emergency, the exit, as you know,  
8 is right behind you. You entered through those doors.

9           So in case there's an emergency, we advise  
10 you that you still have to be escorted, so please don't  
11 try to just run out of the building. We will be leaving  
12 the building together with you.

13           You cannot use the elevators, we will be  
14 using the stairs. There will be hundreds of other  
15 people exiting the building so you won't get lost, I can  
16 promise you that.

17           And there is a general point of assembly  
18 that is behind the building. Again, please try to stay  
19 with your escorts, members of the NRC staff. And we  
20 will all exit in an orderly fashion.

21           So we'll go ahead and get started with  
22 administrative changes. There's just a couple of quick  
23 administrative changes to discuss. I'm on Slide 130.  
24 Addition of reference to 10 CFR Part 76.

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1           So the current definition of substantial  
2 safety hazard, provided in 10 CFR 21.3, admits the  
3 facilities regulated under 10 CFR Part 76.  
4 Certification of Gaseous Diffusion Plants.

5           And the proposed change here is very  
6 simple. It's actually to just add a reference to Part  
7 76 facilities to the definition of substantial safety  
8 hazard.

9           So right there at the end of the definition  
10 of where it discusses the various facilities regulated  
11 under Parts 30, 40, 50, 52, etcetera, we would simply  
12 add, and 76. Part 76 of this chapter. So that's one  
13 of your simple addition here.

14           On the next Slide, 131, and I have to  
15 explain this one a little bit further. The proposed  
16 administrative change that is discussed in the Revision  
17 1 of the draft regulatory basis, a copy of which I hope  
18 you've received, discusses correcting the numbering in  
19 10 CFR 50.55(e)(4), which used to incorrectly reference  
20 Paragraph(e)(4)(V).

21           So what we recently discovered is that,  
22 that particular error, it was a typographical error I  
23 would imagine, because the paragraph I was referencing,  
24 (e)(10), was nonexistent. That particular error was in

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1 fact corrected.

2 So we looked at our most recent references  
3 here in the current regulations book and we found that  
4 Federal Register, Volume 78, published on June 7th,  
5 2013, Page 34248 already states that that correction was  
6 made.

7 So what in fact we're going to do is in the  
8 final regulatory basis, we're going to remove that  
9 administrative change. So I just wanted to inform you  
10 of that, that's already been done.

11 So in fact we are just proposing one  
12 administrative change. We will be correcting that in  
13 the final reg basis.

14 So that's about all I have for  
15 administrative changes. Are there any questions?  
16 Okay. Operator, any questions on the phone?

17 OPERATOR: No questions on the phone.

18 MS. HUCKABAY: Okay.

19 MS. CLARK: Okay, this brings us to our  
20 open discussion. And I think we'll just start and  
21 immediately begin with any questions or comments we have  
22 here in the audience.

23 MR. NICHOL: I've moved over here so I  
24 could see everyone. Mark Nichol, NEI.

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1           So we had the discussion earlier about the  
2 NRC's view that they can't review industry guidance and  
3 it's inextricably linked to the rulemaking. But we did  
4 go back and check and we noted in SECY-11-0135 that the  
5 NRC laid out their plans to do two different paths.

6           One is endorse -- develop or endorse  
7 guidance to provide clarity in that whole second path.  
8 Which would be to develop, you know, to consider  
9 proposed rule language and develop guidance along with  
10 that if it was necessary.

11           So I think the staff had, all the way back  
12 in 2011, envisioned that guidance could be developed,  
13 endorsed and put out for everyone ahead of a rulemaking.  
14 That they weren't inextricably late.

15           So I'd encourage you to go back and read  
16 that provision in the SECY as you consider that. I did  
17 have a second question.

18           I wasn't sure. You laid out your next  
19 step, so after publishing the final reg basis, maybe in  
20 June, you'd go and issue a proposed rule in 2016.

21           Were there any interim steps? Are there  
22 any plans to go back to Commission and seek approval or  
23 provide an update on what the NRC staff is doing?

24           MR. HEATH: The schedule we provided was

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1 very high level with the intent. I have not myself seen  
2 the finalized schedule that lays out those individual  
3 tasks like that.

4 MR. NICHOL: Okay.

5 MR. HEATH: I'm sorry.

6 MR. PRESCOTT: Yes. I think what we can  
7 do, Mark, is -- well this is Paul Prescott, NRO.

8 I think what we can do is get with George  
9 Tartal that's in charge of that and maybe get a more  
10 explanatory agenda of the next steps and see what we can  
11 do there. I'd be more than happy to supply that to you.

12 MR. NICHOL: Okay. I appreciate that. I  
13 just point out, as a note for similar activities is, is  
14 this one where regulatory basis was being developed.  
15 And sometimes the NRC is gone and provided an update to  
16 the Commission prior to moving into the proposed  
17 rulemaking phase.

18 So just give you that for a bit of  
19 information. Thank you.

20 MR. PRESCOTT: Thank you.

21 MR. HEATH: No, I understand. I'm just  
22 not as familiar with the schedule here. I see George  
23 is coming. He's with the Division of Advanced  
24 Rulemaking so he may have some insights here.

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1 MR. TARTAL: This is George Tartal. We  
2 plan to inform the Commission that we finished the  
3 regulatory basis when we're done. As in when we issue  
4 the final, we'll inform them and then we'll move into  
5 the proposed rule phase after that.

6 MR. HEATH: Thank you, George.

7 MR. DUNKELBERGER: Michael Dunkelberger,  
8 MPR. Two comments. One with regard to the  
9 clarification of the proposed language with regard to  
10 the transfer of responsibility upon delivery.

11 I am concerned that the sub or the  
12 supplier's role, the supplier's responsibilities,  
13 aren't clearly defined after the transfer of  
14 responsibility.

15 I think the licensees are going to be left  
16 holding the bag or at least felt as such. Because I'm  
17 concerned that suppliers responsibilities aren't that  
18 all well-defined. Suppliers will have opportunities  
19 to just by the rule, wash their hands.

20 I mean if we don't, you know, if delivery  
21 -- if upon delivery the responsibility for reporting is  
22 now in the hands of the purchaser, then what  
23 responsibility is retained for me for evaluation  
24 reporting purposes.

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1           Is it only to notify the purchaser that I  
2 may have delivered something to you that has a problem  
3 and it's your responsibility to evaluate it?

4           I think the suppliers responsibilities for  
5 evaluation or reporting need to be more clearly defined  
6 in the rule. And that transfer of responsibility could  
7 cause suppliers to just feel like they can wash their  
8 hands of that responsibility.

9           And I think we both agree that, you know,  
10 the suppliers have an important role in evaluating  
11 deviations in determining whether or not we have  
12 defects. We wouldn't want them to feel like they have  
13 a way out by the regulation.

14           MR. HEATH: Right.

15           MR. DUNKELBERGER: The second concern has  
16 to do with comments raised in the draft basis talking  
17 about guidance and an ineffectiveness of the guidance.

18           And it speaks to the questions and answers  
19 from 2008 discussion on Part 21. As being a basis for  
20 saying, well we've seen that guidance is ineffective.

21           And I just feel like it's not a hundred  
22 percent accurate to compare the questions and answers  
23 that came out of that session and how they're posted in  
24 a level of visibility that they have in comparison to

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1 actually issuing a regulatory guidance document, which  
2 I think would have much more visibility in, you know,  
3 the guidance that's more well recognized within the  
4 industry.

5 Does that make sense? Does that comment  
6 make sense?

7 MR. HEATH: I hear what you're saying. I  
8 guess what is -- so what are you proposing or suggesting?

9 MR. DUNKELBERGER: You know, it seems like  
10 the Revision 1 to the draft regulatory basis is  
11 discounting guidance as a viable approach. Because of  
12 the perceived notion that those questions and answers  
13 was a measure of guidance that is thought to be not as  
14 effective as what we would like it to be.

15 But I think to actually issue a regulatory  
16 guide, on Part 21 reporting, would actually be quite  
17 effective. A quite effective means of providing  
18 guidance.

19 And more effective than just having these  
20 questions and answers, which probably not everybody can  
21 easily find.

22 MR. HEATH: Right.

23 MR. DUNKELBERGER: You don't know where to  
24 look. It's harder, you know --

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1 MR. PRESCOTT: This is Paul Prescott to  
2 interrupt. And that's a great point, Mike.

3 One of the things we have to do is, and  
4 that's why NEI submitted a document. Hopefully we can  
5 get that document, find it acceptable to the staff, work  
6 through a reg guide. And that's the ultimate intention  
7 here is to try and get guidance.

8 It's certainly no argument that guidance is  
9 invaluable. Because the regulations are meant to be,  
10 you know, they're not tight enough.

11 And the reason they're not -- never have  
12 been tight, just like Appendix B is, you know, times  
13 change, conditions change. There's fluctuations in  
14 the way things are considered. So they have to -- we  
15 have to be flexible with the times.

16 But we've never really had, we had  
17 NUREG-0302 back in the old days. Part 21. But that,  
18 you know, that was in '77.

19 So we're looking at, you know, it's time  
20 that you do something. And we're glad to partner up  
21 with the industry and find out if we can get a workable  
22 document out there. That's certainly one of the  
23 primary goals of this whole thing.

24 But by the same token we want to make sure

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1 that the new words align with regulations. The new  
2 guidance aligns with regulations. Otherwise you  
3 continue to have a disconnect.

4 MR. DUNKELBERGER: Agreed. I'm just  
5 saying that, to say that the questions and answers were  
6 ineffective means of guidance, that maybe true, but it's  
7 not the same as having an actual reg guide.

8 MR. HEATH: Right.

9 MR. DUNKELBERGER: So sounds good. Thank  
10 you.

11 MR. HEATH: And part of what we're doing is  
12 trying to consolidate where we have stashed a lot those  
13 type Q&As. Because they're kind of all over the place.  
14 I mean NUREG-0302 and then the 2008 Q&A session.

15 MR. PRESCOTT: And after the workshops,  
16 you know, that we had over 200 questions related to Part  
17 21 alone. Again, this is not a way to regulate or  
18 provide guidance.

19 And, you know, for commercial grade  
20 dedications, same story. We have generic Letter 89-02.  
21 We had inspection procedure 38703. Providing the  
22 staff's position.

23 Well that's just not the way to do business.  
24 We're trying to rectify that.

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1 MR. DUNKELBERGER: Agreed. Thank you.

2 MR. WEAVER: Hi, Doug Weaver,  
3 Westinghouse. I'm a little taller so I got to bend down  
4 here.

5 So I'm going to echo the two comments.  
6 Reading the information paper clearly indicated the  
7 staff was on a path four years ago to issue guidance.  
8 So kind of, I think there's a question on the table of  
9 what happened to that.

10 And as well, and I think the, you know, and  
11 the SECY paper acknowledges there was no reg guides and  
12 never have been. So it's hard to know how effective  
13 they would be unless you actually put them in place and  
14 try it.

15 But more -- the comment I really want to  
16 make is, what I haven't heard today is, what's the driver  
17 here. I read the OIG reports, in particular the one  
18 from, I think it's March 2011, and they talk about, well  
19 there was some potentially unreported Part 21s.

20 But they have been submitted to the NRC as  
21 LERs in many cases. But they haven't been flagged as  
22 Part 21s.

23 And so to me that's a very narrow problem.  
24 And I think a relatively easy fix, if that's the basis

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1 for moving forward. So what I'm really trying to  
2 understand is what is the safety basis? What's the  
3 burning platform to do something more than just get the  
4 guidance out there? Thanks.

5 MR. PRESCOTT: Okay. And that's a great  
6 question, thanks for bringing it up. But I think what  
7 I'd like to start out with is, and I'm going to be  
8 reiterating some of these things, so if it sounds like  
9 I'm repeating myself I'm sorry.

10 But one of the key elements of, let's start  
11 with commercial grade dedication. Again, you know, we  
12 haven't had a guidance document that we've found  
13 acceptable through the reg guide process, which is the  
14 appropriate way to do it. And the appropriate way also  
15 is to have an industry document that we work with the  
16 industry, we find acceptable.

17 So that's one piece of it. So we're trying  
18 to take care of that portion of it and get something in  
19 the books. Because as you know, the original 5652 was  
20 conditionally endorsed in 89-02. The generic letter.  
21 So we're trying to rectify that.

22 As far as evaluation and reporting issue,  
23 as I stated earlier, in NUREG-1022, there was one.  
24 There was two sentences related to Part 21. But they

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1 were incorrect in how they had people -- incorrect in  
2 the guidance they provided.

3           Essentially it stated, as I stated earlier,  
4 that it was only for parts on the shelf. Well everybody  
5 knows that that's not a true statement for licensees.  
6 That it can't be much broader than that.

7           And so in NUREG-0302 was another where we  
8 had evaluation reporting. And some Part 21 in that too.

9           And again, you know, it was done through a  
10 NUREG and not a reg guide. And so again, we're trying  
11 to rectify that.

12           And we're happy that NEI is sending a  
13 document for us to review. We fully intend to take look  
14 at that document.

15           And hopefully we can find it acceptable and  
16 go through the reg guide process, just like we're doing  
17 the design and analysis software, just like we're doing  
18 the commercial grade dedication document and just like  
19 we hope to do with the evaluation and reporting. Yes,  
20 sir.

21           MR. LOOMIS: Anything from anybody else?  
22 Okay. Yes, Tom Loomis again from Exelon and is the  
23 chair for the Part 21 industry group here.

24           Just wanted to wrap it up here by saying,

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1 please come meet with us on the NEI document. I think  
2 you -- once you start looking at the NEI document, I'm  
3 sure you're going to find some places where you're going  
4 to look at it and say, eh, we disagree with that.

5 Come to us, talk with us. Sit across the  
6 table from us. It is not a hard fast past position of  
7 what we have. It's the way we view it.

8 Come hear what we have to say. Let's come  
9 to an agreement on it and let's, you know, meet in the  
10 middle. We're more than willing to compromise on it.

11 We feel that the guidance way is a much,  
12 much fairer approach than through the rulemaking  
13 efforts. So before we -- and I think, George, there's  
14 a certain point where, you know, you have to throw the  
15 switch when you can't meet with us.

16 But we're fully willing to meet with you at  
17 any point here. And let's work it out across the table  
18 and figure it out. Please make us accountable for that  
19 document.

20 I mean we're more than willing to say that,  
21 hey, the way we do it is this way. And maybe we might  
22 have to change something or, you know, move things  
23 around or do it that way. But make us, as an industry,  
24 accountable.

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1                   We're more than willing to accept that  
2                   responsibility and make it easier for you guys. I'll  
3                   wrap it from that. From industry's viewpoint here and  
4                   turn it over to the phone.

5                   MR. PRESCOTT: Thank you.

6                   MR. LOOMIS: Thank you.

7                   MS. CLARK: Thank you very much.  
8                   Operator, do we have any questions on the phone?

9                   OPERATOR: Yes, we do. We have three  
10                  participants. The first is Michael Leahy from Exelon.

11                  MR. LEAHY: Yes. Hi, this is Mike Leahy  
12                  for Exelon. Thanks for the opportunity.

13                  I just wanted to revisit for a second Slide  
14                  44. We have talked about this question of where,  
15                  according to what the slide lays out, where does it ever  
16                  engage an evaluation responsibility for the supplier.

17                  You know, if the defect can only occur after  
18                  acceptance and then after acceptance it's the  
19                  evaluation, responsibility is with the customer.

20                  My question is, in the regulation  
21                  revisions, Paragraph 21.21 subparagraph (b), it starts  
22                  off saying, and this is for notification  
23                  responsibility, it starts off saying, if a supplier  
24                  determines it does not have the capability to perform

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1 an evaluation, now then the supplier must inform.

2 So my comment is, it appears as though the  
3 slide discussion, which places all evaluation  
4 responsibility on the customer, is not consistent with  
5 the actual wording, 21.21(b), which recognizes that  
6 there is a evaluation responsibility of the supplier.  
7 And if he can't do it, then it goes to the customer.

8 So I just ask that you scrub, if you will,  
9 or double check for alignment the words that are in the  
10 markup, the rule markup, against possibly the slide.

11 So we're clear, is it really the words in  
12 the rule markup or is it what you're telling us in the  
13 slide and in the end, you know, they'll come together.  
14 That's it.

15 MR. HEATH: I understand. We'll take a  
16 look at that. I can't provide an answer at this time  
17 without, you know, trying to wrack my brain.

18 OPERATOR: All right. In that case our  
19 next comment comes from Robert Marshall of NuScale.

20 MR. MARSHALL: Yes, this is Bob Marshall.  
21 I have a couple of questions here.

22 First I wanted to ask. We've talked a lot  
23 about operating plants and non-reactor facilities and  
24 we're in the creating a BCA process.

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1 I know that the 10 CFR 50, I mean 10 CFR 21  
2 applies to our application, but we've had considerable  
3 confusion over what we might encounter that would be a  
4 CFR 21 reportable incident. Since we don't get --  
5 deliver anything to any site.

6 The problem that we have is there are things  
7 that we may encounter. I should say, the question I  
8 have is, we may encounter defects in products or  
9 services or components that were delivered for us, for  
10 our research or design development and analysis. Not  
11 just software in particular.

12 That would be common software that's used  
13 throughout the industry. If we find the defect in the  
14 sample, from my own experience, was a software developer  
15 that had a defect that they found in their product 20  
16 years after it had been created. It was a  
17 miscalculation of the strength in materials in a  
18 structural software.

19 The consequences for that could have been  
20 significant had it not been detected. And may very well  
21 have undermined the safety of some buildings.

22 The bottom line is, if we were to encounter  
23 such a situation, none of these key words, like  
24 delivered and so forth, may not apply to us. And we've

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1 had discussions as to whether or not we would ever have  
2 a 10 CFR 21 product.

3 Is that a -- do you understand my question  
4 now?

5 MR. PRESCOTT: Yes, I think I understand  
6 your question. This is Paul Prescott, NRO.

7 For the small modular reactors, which is  
8 what NuScale is developing, designing and developing in  
9 considering manufacturing, there is a working group  
10 taking a look at some of these licensing concerns.

11 And this is one we can certainly, we'll pass  
12 that along to them. But I know that there's a group  
13 actively looking at some of the issues related to the  
14 small modular reactors.

15 More specifically the way NuScale is  
16 thinking of providing these facilities to the, to their  
17 customers.

18 MR. MARSHALL: Okay. And then I have one  
19 follow up on that. There's a fourth definition of a  
20 basic component in 10 CFR 21 that's not mentioned in the  
21 slides, wasn't discussed this morning.

22 And that's the application of that  
23 designation to software. Not to software, to design  
24 and analytical activities. Including testing and so

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1       forth.

2                   Design and analytical activities generally  
3       involve software in this day and age.   And I was  
4       wondering if, again, that links us back to the question  
5       I had about software issues being brought up as a  
6       undelivered product, an issue that right come up where  
7       we find that it's common to the industry.

8                   A common software being used throughout the  
9       industry and an error to some that might be a significant  
10      safety risk.

11                  MR. PRESCOTT:   I'm going to try to tear it  
12      back, what you said a little bit.   Essentially I think  
13      your question is, if you believe in software that you're  
14      using that's related to small modular reactors, is --  
15      somehow has implications for, larger implications for  
16      the rest of the industry, should you report.   Is that  
17      what you're asking?

18                  MR. MARSHALL:   Yes.

19                  MR. PRESCOTT:   And my response would be,  
20      yes, I would hope you do that.

21                  MR. MARSHALL:   Okay.   Well that's our  
22      current status, I mean and stance.   I just wanted to  
23      make sure we weren't just spinning out there in nowhere  
24      because it wasn't too clearly identified or too clearly

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1 understood.

2 So that works for me on that. Thank you.

3 OPERATOR: Once again, Star 1 to ask a  
4 question or make a comment. Our next comment comes from  
5 Sidney Bernsen, independent consultant. Mr. Bernsen,  
6 your line is open.

7 MR. BERNSEN: I'm here. Yes, I'm probably  
8 the oldest guy in the group around this, in this  
9 discussion, having been involved intimately in the  
10 development of quality assurance requirements and  
11 familiar with Part 21 and its original intent and its  
12 evaluation.

13 Some of which has been very confusing to me  
14 because it didn't seem, and doesn't seem, to be  
15 consistent with the basic intent of 21.

16 Now I recognize that you've done a lot to  
17 try to help people understand it in this new version,  
18 but there are a couple -- there's several things in it  
19 that disturb me. And I don't have time to enumerate  
20 them in this discussion, so I will write something.

21 But it really bothers me that Part 21 was  
22 primarily focused on suppliers and was not really  
23 intended to cause the licensee, the operator, to do  
24 anything more than they were already doing in their

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1 reporting roles. And even during the construction  
2 phase, 50.55(e) was taking care of problems that were  
3 discovered and were important to that facility itself.

4 The real problem was to make sure -- that  
5 nobody had control of a supplier once the contract was  
6 completed. And if the supplier stumbled into something  
7 or anybody, such as we heard about a computer program,  
8 that that was reported to all the users, as well as the  
9 Commission, so that the same problem could be evaluated  
10 as its impact on all the other facilities.

11 Now that seems to be lost in this when you  
12 have reporting responsibly assigned to the recipient.  
13 That should not be true.

14 The reporting responsibility should be  
15 retained by the supplier. The recipient obviously may  
16 have to be involved in evaluating the safety  
17 significance.

18 But at any rate, I'm really disturbed  
19 because we had a simple process that worked and it kept  
20 getting more complex and more acclimated and redundant  
21 and lacked focus on what was the original intent of these  
22 things.

23 And I am really disappointed that I hear so  
24 much complexity being added to something that was

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1 originally relatively simple. End.

2 MR. PRESCOTT: We'll take your comment  
3 into consideration. But from a historical  
4 perspective, abnormal occurrence reporting was in place  
5 beforehand for the licensees.

6 And I can't get into the minds of the people  
7 who wrote the original intent of Part 21, but I don't  
8 -- I think they would have dropped off the inclusion of  
9 licensees in the Part 21, if they really felt it wasn't  
10 necessary to also capture licensees under that.

11 But to get back to your point. There's no  
12 intention here of trying to release suppliers of their  
13 reporting responsibilities.

14 Quite the contrary. What we're trying to  
15 do is just make a clear line in the sand for, one, the  
16 dedication of items. And that is, that it doesn't  
17 become a basic component until it's accepted and ready  
18 for use in the plant. Otherwise it cannot create a  
19 substantial safety hazard. So there would be no need  
20 to report.

21 And additionally, it just provides -- again  
22 just from a historical perspective, that from what we've  
23 seen, and we've had to have a number of discussions with  
24 the staff internally and there's a long history

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1 associated with that, that, you know, when it comes to  
2 finally who is going to be responsible if nobody picks  
3 up the ball, there has to be a clear delineation or a  
4 line in the sand where all parties can say this meets  
5 expectations.

6 MR. BERNSEN: Well yes, I certainly  
7 understand that the organization that's responsible for  
8 dedicating a commercial product has a responsibility  
9 for reporting.

10 It really should be the user, not a third  
11 party that does the dedication because they don't have  
12 access to the performance history of the product.  
13 Whereas the supplier does.

14 The thing that you really need to get is a  
15 supplier concerned with reporting problems that they  
16 find with their product, and then of course the  
17 organization if they're using a commercial product,  
18 then they can assume that responsibility when it's  
19 incorporated in their work or in their plant.

20 MR. PRESCOTT: All right, thank you, Sid.

21 OPERATOR: No further questions or  
22 comments in the phone queue.

23 MS. CLARK: Thank you. Are there any  
24 additional questions or comments here?

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1 In that case, then we'll move onto our --  
2 the next portion of our presentation. And for that I  
3 will turn over the microphone to Sabrina Atack. Thank  
4 you.

5 Some people will probably need a --

6 MS. ATACK: Okay.

7 MS. CLARK: We'll take a ten minute break  
8 first.

9 (Whereupon, the above-entitled matter went  
10 off the record 1:33 p.m. and resumed at 1:51 p.m.)

11 MS. CLARK: Thank you. Everybody can hear  
12 me, I hope? Yes. Okay, good. We're ready to start up  
13 again, and I am going to turn over this next portion of  
14 our meeting to Sabrina Atack.

15 MS. ATACK: Good afternoon. I'll be  
16 discussing the rulemaking activities as they apply to  
17 fuel cycle facilities. I'm glad to see the room hasn't  
18 entirely cleared out. I'm impressed with that, so  
19 thanks for sticking around.

20 First, we'll start with Section 3 of the  
21 draft regulatory basis, which addresses the lack of  
22 clarity and the definition of basic component for  
23 non-reactor facilities and activities. I expect that  
24 this will be an exciting discussion topic.

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1                   Moving on to Slide 96, for facilities other  
2 than power reactors, a basic component is defined as a  
3 structure system or component, or part thereof that  
4 affects their safety function, that's directly procured  
5 by the licensee, and in which a failure to comply could  
6 create a substantial safety hazard.

7                   The definition is directly tied to the  
8 concept of substantial safety hazards, which the  
9 Statement of Considerations issued with promulgation of  
10 Part 21 identified as an area in which further rule  
11 clarification may be needed in the future.

12                   The statement cited that insufficient  
13 experience had been accumulated to permit the writing  
14 of the detailed regulation at that time, that would  
15 provide a precise correlation of all factors pertinent  
16 to the question of what is a significant, i.e.  
17 substantial safety hazard.

18                   Given the prescriptiveness in the reactor  
19 definition of a basic component, clarification of basic  
20 components and substantial safety hazards have not been  
21 identified as a major need in that area. However, the  
22 implementation of the rule for fuel cycle facilities has  
23 demonstrated an opportunity for improved clarity.

24                   On Slide 97, you'll see the existing

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1 regulatory framework. Oh sorry. I went ahead. So  
2 we're actually moving on to Slide 98 now. I described  
3 the regulatory framework already. The regulatory  
4 issue is that the rule currently lacks clarity and  
5 specificity for the identification of non-reactor basic  
6 components.

7 The definition is difficult to interpret,  
8 but the reactor facility definition for basic component  
9 is specific to reactor terminology and consequences,  
10 such as the fact that the definition references  
11 maintaining the integrity of the reactor coolant  
12 boundary, the ability to shut down the reactor and  
13 maintain it in a safe shutdown condition.

14 The non-reactor definition applies to  
15 multiple facilities and activities, and doesn't include  
16 sufficient specificity, such that varied activities and  
17 facilities can implement the rule consistently.

18 As a result, we've seen difficulty in  
19 applying the definition as written, and we've received  
20 multiple exemption requests and amendment requests to  
21 apply different definitions than those included in the  
22 Part 21 rule for specific facilities.

23 The staff has determined that the lack of  
24 ability to interpret the definition among the fuel cycle

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1 facility applicants and licensees demonstrates a need  
2 to clarify the definition, so that we can assure  
3 appropriate, consistent application of the definition,  
4 and provide regulatory stability within Part 21.

5 As a result, the staff is proposing changes  
6 to Part 21, to clarify the definition of basic component  
7 for fuel cycle facilities that, are subject to Subpart  
8 H of 10 C.F.R. Part 70. There is an exhaustive  
9 description in the regulatory basis for how the staff  
10 came to the particular definition that is proposed, and  
11 we've discussed it at multiple public meetings in the  
12 past three years.

13 Specifically, I won't go into exhaustive  
14 detail in describing the references that we use to pull  
15 into the development of the definition. But some of  
16 those included the Statement of Considerations issued  
17 with promulgation of the Rule NUREG-0302, NRC guidance  
18 related to abnormal occurrences, and Information Notice  
19 91.39.

20 Further, the staff's determination that  
21 chemical hazards associated with the processing of  
22 licensed material should be included in the scope of the  
23 basic component term, is based off of the performance  
24 requirements in Part 70, as well as the memorandum of

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1 understanding between the NRC and OSHA, in which the  
2 agencies agree that the NRC has jurisdiction over  
3 radiological hazards, as well as chemical hazards  
4 associated with the processing of radiological  
5 material.

6 Inclusion of worker hazards is consistent  
7 with the message provided in NUREG-0302, that  
8 identified that the worker is considered a member of the  
9 public, when you refer to the term "public health and  
10 safety." Further, I'd like to identify that the staff  
11 did focus the definition on engineered items, in order  
12 to be consistent with the intent of Part 21, which was  
13 to identify hardware whose failure could result in a  
14 significant impact on facility operability and safety.

15 Now I have heard comments from industry  
16 recommending that the basic component definition should  
17 really be focused in on sole items relied on safety or  
18 IROFS, that prevent or mitigate high consequence  
19 events. I have heard that, and that is not the approach  
20 that the staff took.

21 There are multiple reasons for that, one of  
22 which is the manner in which the performance  
23 requirements align with existing guidance on  
24 substantial safety hazards, and that's based on the

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1 references that I just identified - The Statement of  
2 Considerations, NUREG-0302 and previous staff guidance  
3 - that have been issued relating to substantial safety  
4 hazards.

5 Also, when you look at Part 21 as it relates  
6 to reactor basic components, the definition includes  
7 systems, structures and components, based on their  
8 safety function. The fact that there are multiple SSCs  
9 that contribute to the prevention of substantial safety  
10 hazards does not prevent those SSCs from being  
11 identified as basic components.

12 Therefore, I just want to ask that in terms  
13 of looking at the rule changes and guidance that are  
14 being recommended for fuel cycle facilities, that you  
15 do look at the big picture of everything that is being  
16 proposed, in order to assess how we are applying the  
17 risk-informed and performance-based approaches in Part  
18 70, to improve the clarity of Part 21.

19 On Slide 100, you will see some pictorial  
20 descriptions of what IROFS would be basic components  
21 under the proposed definition, and I have presented  
22 these at previous public meetings in which we discussed  
23 the proposed rulemaking.

24 These just are -- the purpose of these

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1 scenarios is just to give a demonstration of what IROFS  
2 will be a basic component using the proposed rule  
3 language, to provide a little extra clarity, because it  
4 is a bit of a wordy definition.

5 So I thought this would help to give a  
6 little more detail in terms of what IROFS would be a  
7 basic component under the Part 70 infrastructure that  
8 includes administrative and engineered controls.

9 So looking from left to right, you will see  
10 in the left scenario IROFS A is the only IROFS in place  
11 to prevent or mitigate the effects of an event that cause  
12 the performance requirements to be exceeded. In this  
13 case, IROFS A is an engineered IROFS. Then it would be  
14 a basic component, because there are no other IROFS  
15 available to independently prevent or mitigate the  
16 accident that is of concern.

17 In the center of the slide, you will see  
18 another scenario in which you have IROFS A which is  
19 administrative, and IROFS B which is engineered. IROFS  
20 B is capable of independently preventing or mitigating  
21 the accident, and in this case IROFS B is a basic  
22 component.

23 Like I said, in terms of looking at the big  
24 picture for the rulemaking, the definition of a basic

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1 component as proposed does not provide credit for  
2 administrative controls, although they are part of the  
3 Part 70 regulatory infrastructure.

4 Where we draw that credit for the  
5 administrative IROFS is actually in the evaluating and  
6 reporting process, which we'll talk about in subsequent  
7 slides.

8 The far right column identifies a scenario  
9 were you have three IROFS credited for the same  
10 scenario. IROFS A is administrative, B is engineered,  
11 but it's not capable of independently preventing or  
12 mitigating an accident, and IROFS C is also engineered,  
13 but it is capable of independently preventing or  
14 mitigating the accident of concern.

15 So in this scenario, IROFS C would be a  
16 basic component, because it's the only engineered IROFS  
17 whose independent action can insure compliance with the  
18 performance requirements.

19 Moving to Slide 101, we have a few more  
20 scenarios. You'll probably start to get the hang of it  
21 as we go through these, or get really, really tired of  
22 it. But I promise you this is the last slide with these  
23 images.

24 So the left hand column identifies a

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1 scenario in which you have IROFS A, which is an  
2 administrative control. IROFS B is engineered, but is  
3 not capable of independently preventing or mitigating  
4 an accident, and IROFS C is also engineered, but again,  
5 like IROFS B, is not capable of independently preventing  
6 an accident.

7 In that case, both IROFS B and C are needed  
8 in order to prevent exceeding the performance  
9 requirements, and as such both would be basic  
10 components. In the center of the slide, the next  
11 scenario identifies again an administrative IROFS, and  
12 those are just provided in order to demonstrate the role  
13 of administrative IROFS at this point, and the end point  
14 of that is that administrative IROFS are not credited  
15 in terms of identifying what is a basic component or is  
16 not as part of the proposed definition.

17 So in the center you will see an  
18 administrative IROFS, and then two engineered IROFS,  
19 IROFS B and C. B is capable of independently preventing  
20 or mitigating the accident, as is IROFS C. However,  
21 IROFS B and C are identical, and as such they would be  
22 subject to common cause failure. Because of that, both  
23 would be basic components because they do lack  
24 diversity.

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1                   And the last scenario is to the far right.  
2           Again, you have an administrative IROFS and two  
3           engineered IROFS. IROFS B and C are both capable of  
4           independently preventing or mitigating the accidents,  
5           and they are not identical. As such, no IROFS will be  
6           basic components in that scenario.

7                   On Slide 102, it's a little bit of a flow  
8           chart to further depict the process for identifying  
9           which IROFS will be basic components. Starting at the  
10          top, when you have a system structure or component  
11          that's designated as an IROFS and is needed in order to  
12          fulfill the requirements of 70.61, then that would be  
13          a basic component.

14                   Taking the second level of evaluation, you  
15          would look at that item that as of now is a basic  
16          component, and you would evaluate whether there are  
17          redundant engineered IROFS in place to  
18          perform -- capable of performing that same safety  
19          function. If the only controls available are  
20          redundant, such that there's no diversity, then the item  
21          would be a basic component.

22                   If there's an administrative IROFS that  
23          exists that's capable of performing that same safety  
24          function, the item would still also be a basic

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1 component. And then on the far right you would see that  
2 if a diverse engineered IROFS exists that's capable of  
3 performing that same safety function, then the item  
4 would not be a basic component.

5 So now it is time for a discussion of the  
6 basic components term. I will open the floor up to  
7 questions and comments.

8 MR. NICHOL: Sabrina, thank you. This is  
9 Marc Nichol from NEI. So a different face. Janet  
10 couldn't be here today, so I'm filling in. Just a  
11 disclaimer up front. I'm not a fuel cycle facility  
12 expert, so if I say anything incorrect, I've got a bunch  
13 of people that will chime in and correct me.

14 So anyway, I just wanted to first -- sorry.  
15 I wanted to first extend our appreciation. We see that  
16 the NRC has considered industry input today, and has  
17 revised the proposed changes. So we do appreciate  
18 that. We do still have some remaining concerns with  
19 what the NRC is proposing. So just as a general  
20 comment, I'll lay out a few and then I'll see if others  
21 have some specifics.

22 So the main concern really is in tying a  
23 basic component to the definition of IROF, and we think  
24 that that approach would actually be a new position. It

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1 would expand the scope of Part 21, and the reason being  
2 is that not all IROFS could result or could create a  
3 substantial safety hazard.

4 I think there's two main -- so let me start  
5 by -- and first say I understand what the NRC is -- I  
6 believe I understand what the NRC is trying to do, to  
7 provide consistency across the different classes of  
8 licensees, and I think that's important. But I think  
9 there's a distinction or a very big difference between  
10 reactor facilities which tie basic component to  
11 safety-related, and fuel cycle facilities with the  
12 proposal being to tie in basic component to IROFS in two  
13 main areas.

14 One, if I think of an IROFS, I think of it  
15 more as analogous as important to safety for reactors,  
16 which is much different from safety-related. So we  
17 understand it's important to safety. We just don't see  
18 it as safety-related, not all of them anyway. The other  
19 is that the Part 70 rule is -- or the IROFS to meet the  
20 Part 70 rule are risk-informed, or they're on a risk  
21 basis, so they have risks associated with it, and I don't  
22 think that that is -- can be accurately captured.

23 So for example, reactor facilities, the  
24 criteria for, you know, reactor coolant pressure

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1 boundary, those sorts of things, they're all  
2 deterministic criteria, where the IROFS are based on  
3 risk criteria. So I think those two main differences  
4 make it difficult to extend all IROFS into basic  
5 components. So I think there's a small subset of IROFS  
6 that would be basic components.

7 Two other points to articulate our concern  
8 on the NRC proposal. So the other is that if we look  
9 over at say the last 100 reports on degraded IROFS,  
10 because there is a reporting criteria under Part 70 to  
11 report degraded IROFS, when we look at all those, we  
12 can't find any that would have created a substantial  
13 safety hazard. And so that further gives, I think,  
14 emphasis to the idea that not all IROFS should be basic  
15 components.

16 The third point is I believe there's an  
17 unintended consequence if basic components are -- all  
18 IROFS are declared basic components, and that's that a  
19 bunch of other requirements would now need to be imposed  
20 on all IROFS that currently aren't imposed on IROFS.

21  
22 For example, now management measures and  
23 some other type of requirements are applied. So I'm  
24 sure others can help clarify that if need be. But

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1 that's it. Thank you.

2 MS. ATACK: Thanks Marc. I understand  
3 your concerns. I'm not sure if I can go one by one in  
4 addressing them. I think there are a couple of areas  
5 that the staff evaluated in determining what approach  
6 to use to develop this definition.

7 I'm sure all of you who are familiar with  
8 fuel cycle facilities can acknowledge that there is no  
9 easy way to clarify the term, such that it would be  
10 easily translatable between different facilities that  
11 have different technologies, you know, and different  
12 operating structures, and just very, very diverse IROFS  
13 in their facilities.

14 So we chose not to link the definition to  
15 the risk associated with an IROFS, because the ISA, the  
16 Integrated Safety Analysis, is a very flexible process,  
17 such that you could change the IROFS applied to an  
18 accident scenario to apply different IROFS.

19 You're allowed to use engineered and  
20 administrative controls, you know. There's guidance  
21 in NUREG-1520 for identifying the risk reduction, you  
22 know. You know, there's general guidance for  
23 identifying what level of risk reduction can be  
24 attributed to different controls.

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1           But there is the potential that if we were  
2 to make a focus on saying all right, any system structure  
3 or component that is credited with X degree of risk  
4 reduction would be a basic component. Then licensees  
5 would have the flexibility of saying "okay, well I'm not  
6 going to credit any engineered controls with that level  
7 of risk reduction.

8           "I'm going to give them, you know, a power  
9 of ten less than that, and then I'm going to apply a  
10 couple of extra administrative controls, to bump up it  
11 to get myself to the unlikely or highly unlikely place  
12 that I need to be, in order to comply with performance  
13 requirements." So really focusing just on risk  
14 reduction wasn't the best approach to follow for the  
15 definition.

16           So the staff did try to make the most  
17 risk-informed, you know, performance-based  
18 determination of what a basic component should be, and  
19 this was -- this was our best approach. You have to take  
20 into account the evaluation and reporting changes that  
21 we're recommending and guidance.

22           That does hit on one of your other comments,  
23 which is the concern that additional controls would need  
24 to be applied to IROFS, and I do not think that's the

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1 intent of the staff through the rulemaking and guidance  
2 that's proposed.

3 Like you said, we did make some changes from  
4 Revision 0 to Revision 1 of the draft regulatory basis,  
5 and part of that was the outcome of a series of site  
6 visits that we did at fuel cycle facilities, where we  
7 looked at the Part 21 infrastructure and the controls  
8 that are applied by licensees under Part 70 management  
9 measures programs, in order to ensure the availability  
10 and reliability of IROFS.

11 Those would apply to things like the  
12 selection of suppliers, you know, any sort of receipt  
13 inspection, and post installation testing - because we  
14 know that is a big part of the way that fuel cycle  
15 facilities ensure the availability and reliability of  
16 IROFS. We also took a look at types of items that are  
17 being procured by licensees. So we looked at those and  
18 we changed the regulatory basis, to really account for  
19 those processes, and said that the programs that are  
20 being implemented under Part 70 for management measures  
21 are sufficient, in order to ensure the availability and  
22 reliability of IROFS on that forward end, you know, the  
23 design procurement, installation, maintenance.

24 However, we did feel that there's value in

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1 going through the evaluation process and doing  
2 reporting as appropriate. We'll get into that in a  
3 little more detail in the subsequent slides. So the  
4 staff's outcome was that you don't need to change the  
5 way that you treat IROFS in any large way, shape or form.

6 Really, the larger change will be the  
7 identification that they are basic components, and  
8 there will be evaluation in the event that you identify  
9 a deviation associated with those items.

10 And the other point I would like to make is  
11 that the staff intent is only that items that are  
12 necessary in order to comply with the performance  
13 requirements of 70.61 would even be in that evaluation  
14 process for determination that they could be a basic  
15 component.

16 The reason I say that is that I'm familiar  
17 with many licensees who have identified a lot of IROFS,  
18 you know. During our site visits we saw, you know, a  
19 scale that goes from, you know, 40 IROFS for a facility  
20 to thousands of IROFS, and that's just, you know --  
21 that's just a part of how the ISA process works and how  
22 different licensees perform their ISA, and how they  
23 identify IROFS boundaries as well.

24 You know, some might identify the IROFS

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1 boundary as being an entire system, or you could break  
2 that down, such that your IROFS are more on a piece part  
3 basis. So again, that's part of the Part 70 process,  
4 which allows a lot of flexibility. So I forgot where  
5 I was going with that.

6 OPERATOR: Excuse me, I apologize for  
7 interrupting. The amplification is fading in and out.  
8 Do you have a replacement mic?

9 MS. ATACK: There's the question if we have  
10 a replacement mic. No. I think we've gone through all  
11 of the replacement microphones. I think we're on  
12 microphone 18 at this point. Oh yes, I remember where  
13 I was going. Thanks for that interjection. That  
14 allowed me to regain my train of thought.

15 But the intent is only that the IROFS that  
16 are necessary in order to comply with the performance  
17 requirements would be in that evaluation process, to  
18 determine if they're a basic component. So if you've  
19 identified, you know, defense in depth, if you've  
20 identified additional IROFS as part of defense in depth,  
21 that is great.

22 But to the extent that those are above and  
23 beyond what's needed to ensure compliance with the  
24 performance requirements, those would not need to be

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1 designated as basic components, because they're not  
2 needed in order to meet the performance requirements of  
3 Part 70. Okay. Do we have any other questions or  
4 comments in the room?

5 (No response.)

6 MS. ATACK: Operator, do we have any  
7 questions or comments on the phone?

8 OPERATOR: Yes, we do. Our first comment  
9 comes from Bob Link of AREVA.

10 MS. ATACK: We're actually not receiving  
11 speaker input from the telephone.

12 OPERATOR: All right. One moment please.

13 (Off-microphone comment.)

14 MS. ATACK: Oh, okay. So I think we're  
15 going to take a five minute break, to try to fix our  
16 technical issues with the telephone system. So if you  
17 can just bear with us. We're going to try to get the  
18 audio feed working again.

19 MP Let the operator know we're going to  
20 disconnected.

21 MS. ATACK: Operator, we're going to  
22 disconnect and reconnect.

23 OPERATOR: Understood.

24 (Off-microphone comment.)

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1 MS. ATACK: Okay. Participants on the  
2 bridge line will not need to call back in, but the  
3 operator will disconnect and reconnect.

4 (Whereupon, the above-entitled matter went off the  
5 record at 2:14 p.m. and resumed at 2:18 p.m.)

6 MS. ATACK: All right, let's go back live.

7 OPERATOR: All right. We'll go live in  
8 three, two, one.

9 MS. ATACK: Can the participants hear me in  
10 the room? Okay, louder, yeah. Good, good. I have one  
11 on the phone.

12 OPERATOR: This is the operator. You are  
13 loud and clear. Let me just open up one line. One  
14 moment please. Be right with you. Please stand by.  
15 Let's see. William Rogers of Lockheed Martin, can you  
16 hear them?

17 MR. ROGERS: Yes sir.

18 OPERATOR: All right. I think we are good  
19 to go.

20 MS. ATACK: Go ahead, William.

21 OPERATOR: Oh no, he didn't have a  
22 question. That was just a test.

23 (Laughter.)

24 OPERATOR: Thank you however, Mr. Rogers.

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1 Robert Link of AREVA. You have a comment or a question.

2 MR. LINK: Thank you. I guess I'll try to  
3 -- I've got a number of questions or comments, and I'll  
4 try to be brief as requested before. But even starting  
5 with on Slide 98, the regulatory issue, albeit I -- the  
6 first bullet on the rule lacks clarity, specifically for  
7 non-reactor basic components.

8 I might agree with that. We've actually  
9 operated, you know, for going on 30 years without that  
10 clarity, and I have yet to see an example of where the  
11 lack of compliance of a Part 21 fuel cycle facility  
12 occurred.

13 Also, in terms of "licensees interpret and  
14 implement basic component differently," I'm not so sure  
15 we're that different. It really gets back, and we'll  
16 focus a little bit harder on the definition of  
17 substantial safety hazard, because I think that's the  
18 crux of the gap between the industry position and the  
19 staff's position.

20 But I don't think we are that different in  
21 terms of our interpretation of substantial safety  
22 hazard, which leads you to basic component. And the  
23 exemption aspects and the license amendments that were  
24 at least cited in the reg basis, if I understand were

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1 essentially three.

2 One, so for the MOX facility, which is by  
3 rule required to be an Appendix B program, which I don't  
4 think is a valid reason for the other non-Appendix B Part  
5 70 licensees, and the other two were new licenses for  
6 enrichment facilities. I can speak specifically,  
7 because I know that AES, the AREVA request was basically  
8 a need to supply items that simply were not available  
9 in the open global market.

10 That exemption was focused on the front end  
11 of the process, in terms of purchasing. So again, I  
12 don't think that represents a broad issue, especially  
13 for the operating facilities.

14 If I move on to Slide 99, in terms of the  
15 applicable guidance related to substantial safety  
16 hazards, I think we have used at least the four  
17 sub-bullets you mentioned, in terms of the Statements  
18 of Considerations, NUREG-0302, the guidance for normal  
19 occurrences, and I have to admit, I did not go back and  
20 look at 91.39, so I can't speak to that specifically.

21 But if I look at 0302, you know, and you did  
22 make a comment and I realize we've had dialogue on this  
23 issue, that the worker is a member of the public. Yet  
24 0302 very clearly explicitly stipulates, for instance

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1 in radiological, that 25 REM to the worker and 25 REM  
2 to the public, you know, which differentiates those  
3 impacts that would be equal to a substantial safety  
4 hazard.

5 I am disappointed that the staff has  
6 essentially I'll say rejected the suggestion that if  
7 the analogy to performance criteria, in terms of the  
8 equivalence to a substantial safety hazard be employed,  
9 that that maybe would be focused on high consequence  
10 events.

11 It's hard for me to understand how a low  
12 consequence event, an intermediate consequence event,  
13 I'm sorry I misspoke, would be considered a substantial  
14 safety hazard. So the consistency issue clearly is in  
15 question between fuel cycle facilities and our  
16 colleagues in the reactors.

17 If I move on to Slide 100, I'm concerned  
18 that this may cause, this logic, and I think I understand  
19 the logic that you're presenting, and I appreciate  
20 actually the graphical representation. I think it  
21 helps convey the understanding.

22 But it causes -- it could cause an  
23 unanticipated or unwanted outcome, and that is, as I  
24 read this, a licensee could create three administrative

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1 or two administrative, I don't think two or two for  
2 intermediate might work, but multiple administrative  
3 IROFS with no engineered IROFS, fulfill our obligation  
4 under the rule, and yet in my mind actually degrade  
5 safety, because the reliability of the engineered IROFS  
6 are superior to the administrative IROFS.

7 So that unintended consequence is very  
8 noteworthy and should not be dismissed. The idea that  
9 I would admit on 101, I was trying to understand both  
10 the far left and center ones, because if I understood  
11 the logic, if you had diverse and independent IROFS, and  
12 the loss of only one IROFS would still keep us from --  
13 in meeting the performance criteria, would have  
14 expected that, you know, those IROFS would not be basic  
15 components.

16 That's actually what you show in the far  
17 right. So I've got a little bit of confusion in my own  
18 mind there, in that context. I guess the final comment  
19 in this section that I have is in your Slide 102. It's  
20 somewhat, and maybe it's just the graphical  
21 representation, that it's a bit internally  
22 inconsistent.

23 What I mean by that is as you know at the  
24 top you have an SSC designated as an IROFS, and a failure

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1 to detect or failure to comply could cause the  
2 performance requirements to be exceeded, that somehow  
3 those two means you've got a basic component, and yet  
4 you allow further downstream the -- if you need the  
5 diverse engineered IROFS scenario that exists to  
6 perform the safety function, that becomes then it's not  
7 a basic component.

8 So you know, logic tree-wise, I would have  
9 probably moved that upstream in the flow chart. But  
10 that's --

11 MS. ATACK: I probably should have said  
12 potential basic component in the center box to be more  
13 clear.

14 MR. LINK: Yeah. In other words, I'd put  
15 that far right lower box, diverse engineered IROFS exist  
16 to perform safety in -- kind of in a lower box or whatever  
17 you want to call it. So but that's -- if I'm  
18 interpreting it right, I think that's a minor, you know,  
19 graphical issue. But if I'm not, then I need to  
20 understand how I'm missing the point.

21 But really the bottom line in the final  
22 comment is I am disappointed that the staff is still  
23 equating performance criteria to a substantial safety  
24 category. That wasn't in my mind, and at least in the

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1 Statements of Consideration, I'm not aware of anything  
2 in the new Part 70, Subpart H discussion of that, nor  
3 am I aware obviously that 0302 was pre-Subpart H. So  
4 the concept is not even -- was not even born yet.

5 And that's what finally draws me to a  
6 conclusion that at least this proposal, and I will be  
7 interested as we go through the rulemaking process,  
8 assuming this stays as presented, on how the backfitting  
9 and the reg analysis in terms of cost impact on the  
10 facilities will be rectified. Thank you.

11 MS. ATACK: Thanks Bob. Given the nature  
12 of your comments, I'm guessing that there was not a  
13 specific question that you were asking to have a  
14 response to?

15 MR. LINK: Well I guess the only question  
16 I inferred would be if I, if you believe I've got a  
17 correct interpretation of either your graphical  
18 representations, which I do believe are very handy and  
19 helpful, and most importantly the presentation in the  
20 reg guide or the reg basis document.

21 I would say that I'm not a rulemaking  
22 expert. But a lot of what is presented here in this part  
23 of the presentation I think still could be dealt with  
24 in guidance. Now obviously guidance would still have

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1 to go through a backfit review, just as any other  
2 requirement would. But I don't think the rule is broken  
3 necessarily.

4 MS. ATACK: Thanks Bob. I think I'll just  
5 respond with a couple of general comments, and the first  
6 is that, you know, you commented that, you know, the fuel  
7 cycle facilities, the older generation ones have been  
8 operating for 30 plus years, you know, without this  
9 clarity in the rule and there haven't been any issues  
10 identified.

11 That may be true, but at the same time, I  
12 will acknowledge that the staff hasn't been actively  
13 looking for those issues in Part 21 implementation.  
14 The story may be different if we were going out and doing  
15 frequent Part 21 inspections for fuel cycle facilities,  
16 and the staff hasn't been doing that.

17 So I can't say whether or not there are  
18 really any misreports or safety issues that the staff  
19 hasn't identified as a result of inadequate Part 21  
20 implementation, or differences in interpretation of the  
21 rule as it is currently written.

22 So I appreciate your perspective, but from  
23 the staff perspective, I do have a little bit of a  
24 different concern, in terms of needing that clarity in

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1 the rule for consistent implementation.

2 And then in terms of your concern regarding  
3 the linking of the performance requirements to a  
4 substantial safety hazard, there is a lot of detail in  
5 the regulatory basis, and I won't go over it right now  
6 unless somebody actually wants me to.

7 But there is a very close link between the  
8 performance requirements and guidance related to what  
9 a substantial safety hazard is, you know, and it goes  
10 into your 25 REM dose for an adult, you know, which would  
11 be a worker; an exposure of .5 REM to an individual  
12 outside the controlled area.

13 You know, and the radiological  
14 consequences are very consistent with what we've seen  
15 in the abnormal occurrence criteria in NUREG-0302, and  
16 in existing guidance. When you pull out 0302, there are  
17 some additional guidance descriptions that go beyond  
18 what we've pulled into the reg basis, and that goes into  
19 how many failures you would have to consider, in terms  
20 of evaluating to determine if something is reportable  
21 or if something's a basic component.

22 So we didn't pull that in, because of the  
23 way we proposed the definition. But if you look in  
24 0302, you'll see some guidance that identifies that you

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1 can't assume that everything else would function as  
2 designed and credited. So if we were to change the  
3 definition in another way, it may be that you would have  
4 to have two controls instead of one, and those would both  
5 still be basic components.

6 So we did try to apply the most reasonable  
7 process we could to clarify the basic component  
8 definition, and I do acknowledge that you believe that  
9 that could be performed through guidance. But that  
10 doesn't mean that -- the staff's recommendation for  
11 rulemaking doesn't mean that -- we won't end up pursuing  
12 guidance in this area.

13 It's just that the recommendation at this  
14 time is to clarify the rule, such that it's more --  
15 provides more regulatory stability.

16 MR. LINK: Could you clarify why you  
17 included the intermediate consequence equal to  
18 substantial safety hazard?

19 MS. ATACK: That goes back to the  
20 radiological thresholds in 0302, and a lot of the other  
21 guidance documents that are referenced, and imposing a  
22 25 REM dose to the worker and .5 offsite. I think  
23 there's also the 500, I mean excuse me the releases that  
24 exceed 5,000 times of values in Table 2 of Appendix B

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1 to Part 20.

2 And then obviously the chemical  
3 consequences haven't been described in any guidance  
4 documents to date, because Subpart H was promulgated  
5 after Part 21.

6 So there really wasn't a link between  
7 chemical consequences and Part 21, and the basis for the  
8 staff pulling those chemical consequences into the reg  
9 basis was the memorandum of understanding between the  
10 NRC and OSHA, that says that the NRC is responsible for  
11 chemical hazards associated with the processing of  
12 radiological material.

13 So given that those chemical consequences  
14 in the intermediate criteria are actually of more  
15 significant concern than the radiological consequences  
16 of those thresholds, those are included as part of the  
17 criteria for what we would determine to be a substantial  
18 safety hazard.

19 MR. LINK: And I respectfully disagree  
20 that intermediate consequences are equal to a  
21 substantial safety hazard, because I don't see the nexus  
22 that you're trying to cite. I see it -- I see it  
23 regarding the high consequence events, but I don't see  
24 it for low consequence or intermediate consequence

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1 events.

2 MS. ATACK: Okay, thank you. We'll take  
3 comments in the room now.

4 MR. NICHOL: Sabrina Marc Nichol, NEI  
5 again. So I look at this slide and I'm not sure if those  
6 nuances are actually captured in the proposed rule  
7 language that the NRC included in the reg basis. So  
8 specifically if I interpret the proposed rule language,  
9 it would be all IROFS are basic components.

10 In this slide, it looks like there are a  
11 certain set of IROFS that would not be considered a basic  
12 component. And you also mentioned earlier that IROFS  
13 that are created, that aren't necessary to meet the  
14 performance criteria of 70.61, would also not be basic  
15 components. So I don't think the proposed definition  
16 would capture those nuances.

17 So you may want to go back and look and see  
18 if there might be some unintended consequences there.

19 MS. ATACK: Okay. Well yeah, I think the  
20 intent was we had some wording, and I'm trying to trace  
21 down to it, where we had pulled out specificity and let  
22 me see if I can find it.

23 (Pause.)

24 MS. ATACK: Yeah. There's a sentence at

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1 the end of the proposed definition that says "The SSC  
2 is not a basic component, if diverse SSCs but not  
3 redundant SSCs exist, whose independent action could  
4 prevent the performance requirements from being  
5 exceeded." So that sentence was one in which we were  
6 trying to provide that clarity in terms of filtering  
7 which IROFS would be basic components.

8 And also, you know, we identified that it  
9 would be an IROFS, an item that's designated as an IROFS  
10 in accordance with 70.61. But I see what you're saying,  
11 in terms of the fact that we could identify that it's  
12 those IROFS that are needed, in order to meet the  
13 performance requirements, and that would be more clear.  
14 Thank you. Go ahead.

15 MR. WARE: Sabrina, William Ware with the  
16 Southern Nuclear Operating Company. First, a  
17 disclaimer. I'm not that familiar with the  
18 stipulations to the Part 70 licenses. But in the  
19 discussion, you had mentioned risk-informed, and Marc  
20 Nichol had pointed out that for the power reactors,  
21 typically we've used a deterministic classification,  
22 and I was just going to suggest that for consistency,  
23 power reactors have the option of using the  
24 risk-informed, and like for Plant Vogtle, we just got

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1 a license amendment to apply the 50.69, and we're not  
2 sure, you know, in the power reactor world, if that's  
3 going to prove to be a viable option or not.

4 But just, you know, big picture for the  
5 future. Under the risk-informed provisions of 50.69,  
6 for safety-related low risk components, Part 21 does not  
7 apply.

8 So you know, for consistency across the  
9 regulations, if you're looking at risk-informed, you  
10 might consider those provisions in 10 C.F.R. 50.69, and  
11 how those risk categories would correspond to risk  
12 categories for other categories or other types of  
13 licenses, so that those requirements would be  
14 consistent across facilities using the risk-informed  
15 methodology.

16 MS. ATACK: Yeah, we did take a look at  
17 that, and it was difficult to translate 50.69 into the  
18 regulatory infrastructure under Part 70. So yeah, it's  
19 a valuable piece of input, and yeah, I appreciate that.  
20 Thank you.

21 MR. WARE: But like you mentioned, there is  
22 the pitfall of when you make changes in the facility,  
23 you can change your risk categorization, and move in and  
24 out of categories, which would move you in and out of

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1 reportability space. So there are some complications  
2 there. But I was just suggesting that historically,  
3 power reactors have not used the risk-informed. We're  
4 doing some pilots. We don't know where that might go.

5 So you know, just for long-term  
6 applicability of the regulations, you might want to look  
7 at that, just to make sure we're consistent from a  
8 risk-informed standpoint on the different  
9 applications. Thank you.

10 MS. ATACK: Great, thank you. Any other  
11 comments in the room?

12 (No response.)

13 MS. ATACK: Are we completed with the  
14 questions on the phone for this topic?

15 OPERATOR: We actually have three  
16 commenters on the phone.

17 MS. ATACK: Okay, we're ready.

18 OPERATOR: Nancy Parr from Westinghouse,  
19 your line is open.

20 MS. PARR: Hi Sabrina.

21 MS. ATACK: Hi Nancy.

22 MS. PARR: The first comment is basically  
23 a philosophical one, and there was a gentleman in the  
24 audience who was talking about his participation in the

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1 original Part 21 rulemaking, and he expressed some  
2 concerns that these proposed revisions are not really  
3 in line with the original purpose of the rule. I really  
4 look forward to reading his comment letter. So please  
5 do submit that.

6 While I didn't participate in the original  
7 rulemaking, his comments are consistent with how my  
8 predecessors trained me, and as I understand it, and  
9 this is in layman's terms, one of the original purposes  
10 of Part 21 was to quickly inform companies who used  
11 similar safety components, that they procured of a  
12 defect in a component, that could cause problems,  
13 substantial safety hazards at their sites.

14 With all of the reactor community using  
15 many similar safety components, and also having  
16 Appendix B type programs, it pretty much was an  
17 operating experience program, where if you bought a  
18 safety component and there was a defect in it, it was  
19 made wrong in some form or fashion, then you want to get  
20 that word out quickly to the community who uses that  
21 component, because they could have similar problems at  
22 their facility.

23 And in the context of the fuel cycle  
24 facility, and in the context of IROFS, I think we lose

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1 a lot of that original purpose of Part 21. Most of the  
2 fuel cycle facilities do not have Appendix B programs,  
3 our processes and hazards are very different, and so are  
4 our IROFS. So we're not really procuring basic  
5 component, and you know, this issue of having a defect  
6 in a component that we all use is not very likely.

7 And I believe that someone mentioned  
8 earlier, we have looked at the notification reports that  
9 the fuel cycle facilities have reported over the years,  
10 and we have not found any that would have tied to a  
11 substantial safety hazard.

12 The second aspect of my philosophical issue  
13 is getting to the definition of a basic component for  
14 a fuel cycle facility, rather than focusing on the  
15 definition of substantial safety hazard. I would have  
16 like to have seen us work first on the definition of  
17 substantial safety hazard, and then from that,  
18 determine which components meet the criteria for a basic  
19 component.

20 It kind of seems to me like it's that in this  
21 proposed basis, in the reverse order, it's like we said  
22 okay, this is what it to be, basic components. Let's  
23 figure out how we tie that to 10 CFR Part 70 and the  
24 performance requirements.

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1           So in what I think that causes, the problem  
2 that creates, is that it appears to me that fuel cycle  
3 facilities have a lower consequence threshold for basic  
4 components than the reactors do. So that, that kind of  
5 summarizes my philosophical points. I do also have a  
6 very specific question on Slide No. 101.

7           When we are talking -- it's Slide 101, and  
8 we're looking at the independent criteria for IROFS, I'm  
9 wondering what the definition of independence is, and  
10 the example I would give if IROFS A were controlling  
11 level, and it was using one technology such as like a  
12 differential pressure bubbler, and IROFS B also is  
13 measuring level control, but it's using some, you know,  
14 source or radiometric technology, are those two  
15 different IROFS considered independent?

16           MS. ATACK: Yeah, Nancy. For the  
17 description you provided as an example, I would consider  
18 those to be independent IROFS, because they're using  
19 different technology to perform the needed safety  
20 function of monitoring the level.

21           MS. PARR: Okay, good, and that's all I had  
22 to say.

23           MS. ATACK: Other comments Nancy?

24           OPERATOR: Two more commenters from the

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1 phones. If possible, our next commenter is Scott  
2 Murray of Global Nuclear Fuels.

3 MR. MURRAY: Hi Sabrina, it's Scott  
4 Murray. I noticed there was a subtle but very  
5 significant shift going from Slides 100 and 101, and  
6 then when I get to Slide 102, there in the upper right  
7 hand it talks about a defect or a failure to comply could  
8 cause the performance requirements of 70.61 to be  
9 exceeded.

10 Previously, you were talking about  
11 preventing and mitigating an accident. Was that an  
12 intentional redefinition, or are we using the term  
13 "performance requirements" consistently?

14 MS. ATACK: Yeah, I think that was  
15 unintentional. It was just two different ways of  
16 looking at the way to assess if something is a basic  
17 component or not. I think in the previous slides, the  
18 idea was that you would have assessed the IROFS needed  
19 in order to comply with the performance requirements as  
20 a result of the ISA process in which you analyzed  
21 accident sequences.

22 MR. MURRAY: Well let -- let me try to help  
23 then, because I'm very confused or I'm concerned that  
24 we're looking at the consequences, you know, the things

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1 that happen in 70.61 that define a high consequence  
2 event, such as the dose and other things that you've been  
3 talking about. But in reality, 70.61 describes the  
4 risk of these credible high consequence events must be  
5 limited due to use of controls, to make them highly  
6 unlikely.

7 And I think as you understand, the term  
8 "highly unlikely" for most of the existing facilities  
9 was defined and accepted by NRC as basically less than  
10 or equal to 10 to the minus 4 events per year. And the  
11 loss of one more IROFS simply means you no longer meet  
12 that performance requirement.

13 In other words, the arithmetic risk now  
14 changes from 10 to the minus 4 to something like 10 to  
15 the minus 3, or 10 to the minus 2. It concerns me,  
16 because if you look at Appendix A, that simply means  
17 that's an event report, but it does not necessarily mean  
18 that you've now created a substantial hazard.

19 In other words, on Slide 102 I would have  
20 thought it would have been much clearer, and maybe  
21 throughout the rulemaking, if what you meant was the  
22 effect or failure to comply could cause a high or  
23 intermediate consequence event, because that's I think  
24 what you've been talking about, not merely the fact that

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1 the performance requirements are exceeded.

2 MS. ATACK: I think that I -- one second,  
3 let me make some notes, Scott.

4 MR. MURRAY: And I'm concerned, because  
5 the term "performance requirement exceedance" is very  
6 different than for a fuel cycle facility under Subpart  
7 H, than for example on the reactor side, where they're  
8 worried about true risk, for example, loss of a  
9 containment boundary or core damage or some shutdown  
10 margin.

11 Our performance requirement exceedance  
12 simply means we've gone from that arithmetic risk of  
13 highly unlikely to something more than that, 10 minus  
14 4 to 10 minus 3.

15 MS. ATACK: Right, and I think the intent  
16 would be that the basic components are those IROFS that  
17 are needed to ensure compliance with the performance  
18 requirement, and it's not that the only items that would  
19 be basic components are the one where if it fails, you're  
20 going to have a significant event.

21 MR. MURRAY: Well then we need to have a lot  
22 more debate about this during the rulemaking, because  
23 that is a significant change and I think, as several  
24 people pointed out, a significant difference in the

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1 way we've applied our ISA. We use a number of IROFS,  
2 both administrative and engineered, to meet performance  
3 requirements.

4 And the loss of any one of those simply  
5 means you no longer meet that arithmetic risk. You do  
6 not in fact, as a result, create a substantial hazard.

7 MS. ATACK: Right. I think that's  
8 consistent --

9 MR. MURRAY: So if that's really what you  
10 meant throughout this, and that's what you've used  
11 further throughout, on Slide 102 and on, then like I  
12 said, I think we need to continue to pay very close  
13 attention to this, because that's not the way we've  
14 applied our ISA or I think intended to apply Part 21 to  
15 it in the past.

16 MS. ATACK: Yeah, and I think that the  
17 intent of Part 21 is not that basic components are only  
18 items where you would have a failure and immediately  
19 have some consequence to the worker or the public. I  
20 think both within reactors and fuel cycle facilities and  
21 other facilities regulated under Part 21, basic  
22 components are part of the overall safety equation at  
23 a facility.

24 I don't think that a basic component should

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1 be something that's just the last layer of protection  
2 from, you know, a chemical release or, you know,  
3 criticality accident. I don't think that's an  
4 appropriate way to identify basic components.

5 MR. MURRAY: Well I think again, we may be  
6 talking past each other still Sabrina, because the term  
7 "performance requirement" is not the event. The term  
8 performance requirement in 70.61, I believe, is a simple  
9 arithmetic risk factor, to cause something to become  
10 highly unlikely. For most existing facilities, it's 10  
11 minus 4.

12 And I don't understand how the exceeding  
13 that performance requirements, 10 minus 3 by itself is  
14 a substantial safety hazard. You're still 1 in 1,000  
15 a risk factor. We'll have to flush this out through  
16 rulemaking apparently. That's all.

17 MS. ATACK: Okay. Thanks Scott. I mean  
18 yeah, there may be some lack of clarity in the wording  
19 I've used on the slides. But I guess my train of thought  
20 was such that in the Integrated Safety Analysis process,  
21 you evaluate all credible accident sequences, and then  
22 identify the IROFS that are needed in order to prevent  
23 or mitigate the consequences of those accident  
24 sequences, in order to comply with the performance

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1 requirements.

2           And that correlates to the discussion we  
3 had a little bit earlier, where we're really looking at  
4 those basic -- those IROFS that are necessary in order  
5 to ensure compliance with the performance requirements,  
6 to determine which ones will be a basic component.

7           So like you said, there are a lot of IROFS  
8 that are in place, and the consequence of one failing  
9 may simply be that you're less protected from a  
10 consequence than actually having the consequence. But  
11 that is part of the proposed definition that the staff  
12 has provided. It's not that a basic component will be  
13 an IROFS whose failure would result in a direct accident  
14 and would definitely result in a specific hazard.

15           It's something that the licensee has  
16 determined is necessary in order to ensure safety at the  
17 facility, such that the performance requirements could  
18 be met. Those items would be basic components. But  
19 again, it's only those that are necessary in order to  
20 ensure compliance with the performance requirements.

21           So if you have multiple IROFS, and again  
22 taking into account the engineered administrative  
23 portions of the proposed language, if you have multiple  
24 IROFS, engineered IROFS for instance that are diverse

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1 in nature, then none of those would necessarily need to  
2 be basic components, consistent with what's provided on  
3 the slides, if those are independently capable of  
4 preventing or mitigating the accident that you analyzed  
5 in the ISA and determined that you needed those IROFS  
6 in order to meet the performance requirements, to limit  
7 the risk.

8 OPERATOR: We have one comment from  
9 Charles Slama of Urenco. Your line is open.

10 MR. SLAMA: Hey Sabrina.

11 MS. ATACK: Hi Chuck.

12 MR. SLAMA: I guess real quick, going back  
13 on this discussion that's been ongoing, it seems to me  
14 that we did not -- well, this is kind of hard for me to  
15 explain, I guess, without my ISA folks here. But we do  
16 our ISA analysis to determine whether we need an IROFS,  
17 to not only reduce the likelihood, but also mitigate the  
18 consequences should an accident occur.

19 So if I -- the way that we've always  
20 approached this is if I have a component out there, and  
21 I find out that there's something, that there's a defect  
22 that exists due to manufacturer error, specifically  
23 with their implementation of their QA program, and I  
24 find out that that defect, should that postulated

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1 accident sequence occur, that the IROFS would not  
2 perform its safety function, I would exceed either  
3 intermediate or high consequence, either the likelihood  
4 or the consequences, then that's definitely something  
5 I need to report out in Part 21.

6 I don't know. It's just I'm kind of lost  
7 in the misunderstanding that exists, maybe from some of  
8 the other facilities. But what I want -- the other  
9 thing I wanted to talk about, on your tables on Slides  
10 100 and 101, it seems to me that a lot of these IROFS,  
11 if you're saying that you have an administrative IROFS  
12 and an engineered IROFS capable of independently  
13 preventing or mitigating an accident sequence, then why  
14 would you have --

15 If something is not going to be a basic  
16 component, then that tells me that it probably doesn't  
17 need to be an IROFS, because it's not necessary to meet  
18 the performance requirements of 70.61. I think maybe  
19 they're -- maybe it's just there's an extra layer of  
20 IROFS on here that don't need to be here, and maybe in  
21 some cases it's just defense in depth and doesn't  
22 necessarily need to be defined as an IROFS.

23 In the case of two IROFS that are required  
24 due to their failure probabilities, yes, I can see where

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1 two IROFS would be required to meet the performance  
2 requirements, that is the likelihood and consequence  
3 mitigation. But if they are independent IROFS and only  
4 one of them is needed, maybe there's some confusion in  
5 adding that whole extra level of IROFS for defense in  
6 depth, that's not required to meet performance  
7 requirements.

8 MS. ATACK: Thanks Chuck, and I think what  
9 I've heard in some situations is that there are  
10 different philosophies in determining which items  
11 should be designated -- items and controls should be  
12 designated -- as IROFS.

13 Some facilities will err on the  
14 conservative side, such that if they have an IROFS that  
15 is found to be unavailable, there are additional IROFS  
16 that are designated in that sequence, such that they  
17 wouldn't have to make a report under Part 70.

18 MR. SLAMA: Okay. Well I guess my  
19 argument would be then if there's a failure probability  
20 they're concerned about, then both of those IROFS would  
21 have to be basic components, because if one of them  
22 failed within some frequency that wasn't acceptable to  
23 meet performance requirements, then you're depending on  
24 that other one to account for that failure probability.

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1 MS. ATACK: Thank you. Do we have other  
2 comments or questions from the phone?

3 OPERATOR: No further comments or  
4 questions from the phone.

5 MS. ATACK: Hey, we made it through the  
6 basic component discussion. I think we all knew that  
7 was going to be the worst of the -- well hopefully that  
8 will be the worse of the -- sections that we'll be  
9 discussing for fuel cycle facilities.

10 So I do appreciate the active discussion  
11 and the comments, and we'll definitely consider them  
12 moving forward, as we finalize the regulatory basis, and  
13 then enter into the proposed rule phase and start  
14 drafting guidance, which will be a large part of the  
15 equation for fuel cycle facilities.

16 Next we'll discuss Section 15 of the draft  
17 regulatory basis for evaluating reporting, and the  
18 subject is lack of clarity in the evaluating and  
19 reporting requirements for Part 70 licensees.

20 As you can see, 10 C.F.R. 21.21 describes  
21 the evaluating and reporting requirements for entities  
22 that are subject to Part 21, and the requirements do  
23 state that entities to which Part 21 applies must  
24 develop procedures to evaluate deviations and failures

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1 to comply, to identify defects and failures to comply  
2 that could create a substantial safety hazard if they  
3 were to remain uncorrected.

4 Moving on to Slide 105, you'll see the  
5 existing regulatory framework. This regulatory  
6 framework slide talks about the promulgation of Subpart  
7 H to 10 C.F.R. Part 70, which most of you who have had  
8 a participating role in this discussion are very  
9 familiar with.

10 In 2000, the NRC amended Part 70 to  
11 incorporate new requirements for the development of an  
12 Integrated Safety Analysis for fuel cycle facilities  
13 that are authorized to possess greater than a critical  
14 mass of special nuclear material.

15 In the development of Subpart H, the  
16 Commission did seek to apply risk-informed and  
17 performance-based approach, that included the  
18 identification of performance requirements for the  
19 prevention of accidents, or the mitigation of their  
20 consequences, as well as the performance of an  
21 Integrated Safety Analysis to identify potential  
22 accident sequences at the facility and the items relied  
23 on for safety needed in order to maintain the risk to  
24 an acceptable level.

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1           The implementation of a system of  
2 management measures was also part of the promulgation  
3 of Subpart H to 10 CFR Part 70, and the goal of the  
4 management measures program is to ensure that items  
5 relied on for safety are available and reliable to  
6 perform their safety function when needed.

7           As we've discussed in the past hour, the  
8 existing regulatory infrastructure under Part 70 does  
9 provide a high level of flexibility to licensees in the  
10 conduct of their Integrated Safety Analysis, as well as  
11 the determination of what controls need to be items  
12 relied on for safety.

13           The regulatory issue we have in the  
14 evaluating and reporting regime for fuel cycle  
15 facilities is that there's a lack of clarity as to  
16 whether the implementation of Part 21.21 does enable  
17 consideration of the risk-informed and  
18 performance-based approaches, like those implemented  
19 in 10 CFR Part 70.

20           To date, there's been limited guidance  
21 available for evaluating and reporting for fuel cycle  
22 facilities, so it has been difficult for stakeholders  
23 to understand how to perform evaluations under the  
24 existing regulatory framework.

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1           The staff does believe that consideration  
2           should be given to aligning Part 70 and Part 21, in order  
3           to ensure regulatory clarity and stability. As such,  
4           the staff is proposing to prepare guidance related to  
5           Part 70 evaluating and reporting. The guidance will  
6           delineate when licensees should conduct an evaluation,  
7           and how that evaluation can be performed in a manner that  
8           allows credit for the risk-informed performance-based  
9           approaches defined in the Part 70 regulatory  
10          infrastructure.

11           A diagram -- excuse me. A diagram is  
12          provided on the next slide to provide further  
13          clarification of the proposed process. We are now on  
14          Slide 109, and in this diagram you'll see a flow process,  
15          in which you start with a deviation in an IROFS that has  
16          been identified as a basic component.

17           So you can take two flow paths. The first  
18          will be during the evaluation, you determine that  
19          administrative IROFS are available, that would have  
20          prevented the performance requirements from being  
21          exceeded. In that case, that is the deviation is not  
22          a defect, no report to the NRC is required under Part  
23          21, and the only thing that the licensee needs to do in  
24          order to comply with Part 21 is to retain the documented

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1 evaluation that was performed.

2 On the right-hand side of the flow process,  
3 you would see an evaluation in which an administrative  
4 IROFS was either not designated or was not available to  
5 prevent the performance requirements from being  
6 exceeded. In that scenario, you would have a defect  
7 that's reportable under Part 21, and consistent with  
8 Part 21 requirements, you would also retain the  
9 documented evaluation.

10 Now it is time for questions on the proposed  
11 guidance for evaluating and reporting for fuel cycle  
12 facilities. Do we have any questions in the room?

13 MR. SCHILTHELM: So this is Steve  
14 Schilthelm with B&W. If you go back to your last slide,  
15 109, and then you think about the purpose of Part 21,  
16 Part 21, at least what we've heard throughout the day,  
17 was to get information out to other users, other  
18 licensees, about things that could impact them at their  
19 site.

20 If you look at this slide, it kind of  
21 illustrates the point that it appears as though for fuel  
22 facilities, you're trying to implement an ancillary  
23 event reporting system, because this is very  
24 site-specific. It wouldn't necessarily inform other

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1 licensees, who may be using a component differently.  
2 It's just a very site-specific criteria that says I do  
3 or don't have to report under Part 21.

4 But that doesn't seem to align with the real  
5 intent of Part 21, which is to get information out to  
6 other licensees and other users. So it seems to be a  
7 disconnect.

8 MS. ATACK: Yeah, and I think the flow  
9 chart doesn't speak to those elements of Part 21. I  
10 think there are two aspects in which that function would  
11 be performed after a report is made. The first would  
12 be similar to what Nancy Parr mentioned, you know, in  
13 terms of an operating experience program. Our  
14 licensees are continuously monitoring Part 21 reports  
15 and other reportable events, to determine if there's  
16 anything applicable to their facilities, and I know the  
17 fuel cycle industry does participate in, you know,  
18 biweekly calls.

19 So there's some degree of communication  
20 that occurs, such that the industry can share  
21 information to determine if there's an issue that might  
22 be relevant across the board to more than one facility.  
23 The other part is what happens at the NRC, when we  
24 receive a Part 21 report, and we will assess that Part

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1 21 notification, gathering the additional information  
2 we need with the licensee or the vendor, and then  
3 determine if any further regulatory action is needed.

4 That could take place in the form of an  
5 inspection, that could be a generic communication, you  
6 know. It could be an information notice that says okay  
7 licensees, we've had failures in this type of a  
8 component. This was of safety significance. You  
9 should evaluate if there's any significant -- excuse  
10 me, any similar item in use at your facility, and if  
11 there is, consider taking appropriate actions that will  
12 be relevant to the safety performance for your facility.

13 That's how the Part 21 reports are used in  
14 order to improve safety, though you know, it's the  
15 expectation that licensees would be aware of those Part  
16 21 notifications, and are actively looking at them.  
17 But it also takes place here at the NRC, and it's also  
18 our role to evaluate them and determine if need to do  
19 any further outreach to the industry.

20 MR. SCHILTHELM: But in this particular  
21 slide, as you go down the left-hand chain, depending on  
22 site-specific use of a component, NRC would not be  
23 notified. So that you're getting into a very  
24 site-specific use space, versus generic implication

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1 space I guess is the point I'm trying to make.

2 MS. ATACK: That's true, and yeah. And  
3 it's difficult to find the perfect equation that would  
4 allow us to receive notification of failures that may  
5 affect other licensees who are using things  
6 differently. So I do acknowledge that there are  
7 potential missed opportunities for information to be  
8 shared as a result of this infrastructure.

9 But again, the staff would be able to look  
10 at those evaluations during the inspection process,  
11 when inspectors are on site, and at that time the  
12 inspectors could have the potential to identify  
13 something that may be applicable to multiple licensees,  
14 and could take that back for further action, to  
15 communicate it.

16 MR. NICHOL: Marc Nichol, NEI. Just a  
17 procedural question. So in this and a couple of other  
18 -- of your other issues, you identified proposed  
19 guidance. So could you elaborate on what the NRC's  
20 plans are and status for developing the guidance? Is  
21 it going to be one guidance document, multiple  
22 documents?

23 MS. ATACK: The plan is that it would be --  
24 the two draft guides that have been identified, 1291 and

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1 1292 for accompanying the proposed rule would contain  
2 all of the relevance guidance for Part 21 evaluation,  
3 excuse me, evaluation and reporting and commercial  
4 grade dedication respectively.

5 So the goal would be that the staff would  
6 provide, you know, potential endorsement of industry  
7 documents, as well as specific implementation guidance,  
8 like what we're discussing during this presentation, as  
9 part of those reg guides.

10 Do we have any question -- oh, one other  
11 question in the room.

12 MR. WEAVER: Hi, Doug Weaver,  
13 Westinghouse, and maybe this is a simple question. But  
14 can you give an example.

15 When would you have something that's  
16 reportable under this guidance that you've outlined in  
17 this slide, and not be reportable under, I guess it's  
18 70.74? You know, if you have an IROF that's degraded,  
19 so that you can't meet your -- isn't that already  
20 reportable I guess is my question, and what additional  
21 types of things are you capturing here? Thanks.

22 MS. ATACK: I think what Part 21 really  
23 captures that's not in the existing reporting  
24 requirements under Part 70, and I think this statement

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1 is true for many of the reactor scenarios and someone  
2 can correct me if I'm wrong. But it's really before you  
3 have a failure, you know. It would be something that,  
4 you know, it's a deviation.

5 So it's much further upstream than what you  
6 would find in many of the other reporting requirements.  
7 So it's something that has the potential to cause an  
8 issue if it remains uncorrected. So it could be  
9 something as simple as "we procured a tank and we thought  
10 it was a certain material, but it turns out that it  
11 wasn't."

12 Or "we installed something and we thought  
13 the welds were great, but they're not." Or "we just,  
14 you know, we determined during maintenance that we have  
15 a lot of issues with the welds that were credited with  
16 part of performing the IROFS function for this system."  
17 So those are the -- to me -- the most significant things  
18 we would catch as part of Part 21, that you wouldn't  
19 catch further downstream in the reporting requirements.

20 Do we have any questions on the phone?

21 OPERATOR: We do. Bob Link from AREVA,  
22 your line is open.

23 MR. LINK: Thank you. Slide 109, again if  
24 I'm interpreting it correctly, appears to be

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1 inconsistent with what you presented in the previous  
2 section of the discussion.

3 That is, in the evaluation boxes, do you  
4 really mean just administrative IROFS, though other  
5 IROFS are evaluated within the context of the evaluation  
6 for Part 21? I would have expected you to say  
7 administrative IROFS and/or independent diverse  
8 engineered IROFS are not designated or available to  
9 prevent a performance requirement.

10 You're exclusively saying administrative  
11 IROFS, which is --

12 MS. ATACK: Yeah. We're showing how  
13 administrative IROFS are credited in the evaluation  
14 process, because they're not credited in terms of  
15 identifying what should be a basic component.

16 So, and I'd have to go back and really take  
17 a sharp look at this. But I think the intent was that  
18 if something is a basic component, if an engineered  
19 IROFS does meet the criteria to be a basic component,  
20 then you wouldn't be in the evaluation process able to  
21 find another engineered IROFS that would perform that  
22 safety function, because if that were the case, it  
23 wouldn't be a basic component in the first place.

24 MR. LINK: Well now I am confused, but with

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1 regard to the earlier examples, but I think we can  
2 discuss that further.

3 The other aspect in terms of reporting,  
4 actually you're kind of alluded to in this section, and  
5 that is the question I had earlier today, relative to  
6 whether or not, you know, 70.50, Appendix A reporting  
7 and even 71.95 would if the licensee explicitly included  
8 that it's reporting at Part 21, and provided all that  
9 information as necessary by the rule, I would expect  
10 that those would satisfy the Part 21 reporting  
11 requirements.

12 MS. ATACK: That's true. Thanks for  
13 looping back on that Bob. I did have a note to follow  
14 up on it. So there's, like we said earlier, there's no  
15 specific provision for Part 70 licensees specifically.  
16 But if you look under 21.21(d) in the existing rule, it's  
17 -- I'll read it for you if you give me one second.

18 (Pause.)

19 MS. ATACK: So in short, I'm sorry. Let me  
20 find it.

21 (Pause.)

22 MS. ATACK: It's 21.21(d)(2), states that  
23 "The notification to the NRC of a failure to comply, or  
24 of a defect under paragraph (d)(1) of this section, and

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1 the evaluation of a failure to comply or a defect under  
2 paragraphs (a) (1) and (a) (2) of this section, are not  
3 required if the director or responsible officer has  
4 actual knowledge that the Commission has been notified  
5 in writing of the defect or failure to comply."

6 So that's the citation that provides credit  
7 for reports that have already been made, and again I'd  
8 like to loop back to the importance of identifying that  
9 the report that's being made is also a Part 21 report.

10 So if you do make a report under another  
11 reporting requirement, in order to notify the staff that  
12 that does also serve the function as the Part 21 report,  
13 we would expect that you provide all the necessary  
14 information consistent with the Part 21 reporting  
15 requirements, and also identify that it's a Part 21  
16 report.

17 MR. LINK: Okay. I think you said yes.

18 MS. ATACK: Yes, I did say yes.

19 MR. LINK: And I don't want to belabor it,  
20 but I'm still trying to make sure that I understood maybe  
21 your scenario back on Slide, I'm going back now, 101 far  
22 right, where you had no IROFS for basic components. So  
23 if I have a failure of A or C or B or C I should say in  
24 that scenario, back to your Slide 109, that is or is not

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1 reportable?

2 MS. ATACK: Let me see if I understand your  
3 question Bob. You're saying on Slide 101, the far right  
4 column, if you have a failure of IROFS B or C, you're  
5 asking if that would be reportable?

6 MR. LINK: Correct.

7 MS. ATACK: No, because neither B nor C are  
8 basic components, because in the absence of B, C would  
9 be available to perform the safety function. In the  
10 absence of C --

11 MR. LINK: Because that gets back to my  
12 concern that I stated before, with on 109 just stating  
13 administrative IROFS, rather than administrative  
14 and/or engineered IROFS that are basic components I  
15 guess is the issue. Anyway, it's going to be a  
16 challenge for both of us to write good guidance to be  
17 able to implement that in a consistent way.

18 MS. ATACK: True, and I will think about  
19 that one. Obviously, we have a lot of time that we will  
20 be spending in terms of preparing the guidance. I  
21 understand your point. What I'll have to think about  
22 is if there are any situations in which you would have  
23 a basic component when you -- in your evaluation, you  
24 would consider the availability of other IROFS that are

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1       engineered.

2                   Because like I said, I think in these  
3 slides, you know, 101 and 100, which precedes it, you  
4 actually go through the process of evaluating how many  
5 engineered controls you have available that are capable  
6 of performing the safety function that's credited in the  
7 ISA.

8                   So that part actually accounts for the  
9 additional engineered IROFS that are available, such  
10 that you wouldn't need them in the evaluation process,  
11 but I could be wrong on that. So I'll definitely take  
12 a closer look at it, and I'm sure we'll have more  
13 discussion as we talk about preparing guidance.

14                   MR. LINK: And just to be clear, I guess my  
15 -- you know, one of the significant administrative  
16 burdens that this definition, I'm going back to the  
17 definition again I acknowledge, would indicate, would  
18 mean that every licensee under Subpart H would have to  
19 go back and essentially rescreen each and every IROF and  
20 each and every scenario, to create an understanding of  
21 what IROFS are basic components and which are not.

22                   That is a -- and then obviously it's a  
23 living process, so as we change, either adding IROFS or  
24 changing out IROFS or deleting IROFS, that would change

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1 what becomes a basic component under this proposal.

2 MS. ATACK: That is true. Thank you, Bob.  
3 Yeah, part of the flexibility that's inherent to the ISA  
4 process and the change processes that are available for  
5 performing and updating the ISA, would provide such that  
6 -- the situation such that -- you would have the  
7 potential for having a change to what items are  
8 considered basic components over time, as was  
9 previously mentioned in the comments.

10 So yeah. That's something we'll have to  
11 look at as we move forward. Any other questions on the  
12 phone or comments?

13 MR. LINK: We'll just add it to the cost of  
14 implementation.

15 OPERATOR: Scott Murray of Global Nuclear  
16 Fuels, your line is open.

17 MR. MURRAY: Yeah, I appreciate that. Bob  
18 actually took some of my question that I said I was  
19 confused by the idea of administrative IROFS in the  
20 scheme of things.

21 I will point out that this also tends to set  
22 up a separate additional reporting criteria, not  
23 related to performance requirements, because there are  
24 certain criteria that make something not reportable.

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1 ISG-12, for example, that allows crediting other  
2 controls, and they're not administrative. So Sabrina,  
3 this needs a lot of help, I think.

4 The one other comment I can make, we rarely  
5 use purely administrative controls to meet performance  
6 requirements. We can. Administrative controls  
7 usually only have a 1 in 10 reliability factor. So you  
8 theoretically for our -- to make something highly  
9 unlikely, we need four of them. But the unintended  
10 consequence here is that we could theoretically add  
11 additional administrative controls, and still meet  
12 performance requirements.

13 So even if that original engineered IROFS  
14 was a basic component, this would seem to imply that I  
15 could have multiple administrative IROFS in addition  
16 to that one, and it would not be a defect. So that this  
17 slide is very awkward to understand, and as Bob pointed  
18 out, we would have to go back and reanalyze many of our  
19 IROFS and accident sequences, to even see how this could  
20 apply. A lot of work on this one.

21 MS. ATACK: Thank you, Scott. Yeah, I  
22 think there would be differing levels of work, depending  
23 on how the licensee has conducted the ISA and the  
24 outcome, in terms of how many IROFS were identified,

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1 such that if the licensee only identified the IROFS that  
2 are necessary for compliance with the performance  
3 requirements, that evaluation of what would be a basic  
4 component would be a bit more simple than the licensee  
5 who may have gone and credited several IROFS to provide  
6 defense in depth, even though not all of those are needed  
7 in order to meet the performance requirements.

8 So yes, there's some potential that  
9 additional evaluation would be needed, in order to  
10 determine what would be a basic component. I am aware  
11 of NRC guidance that allows crediting items that are not  
12 identified as IROFS, and I think that would be something  
13 that we would address, as part of the guidance  
14 development.

15 MR. MURRAY: Thank you.

16 MS. ATACK: Any other comments or  
17 questions on the phone?

18 OPERATOR: Charles Slama of Urenco, your  
19 line is open. Mr. Slama, your phone might be muted.

20 MR. SLAMA: You're right. Hey Sabrina,  
21 now that we've had some further discussion, I think I  
22 can clarify what I was trying to say during my last  
23 comment.

24 When I read these scenarios, specifically

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1 situations where we have two independent engineered  
2 IROFS that can independently meet the safety function,  
3 you've said that neither of those would be a basic  
4 component, because any of those independently will meet  
5 the performance requirements.

6 But it's my understanding that most times  
7 where you have two engineered IROFS like that, they're  
8 independent for common cause failures, and that's  
9 because of their failure probabilities. So you do need  
10 both of them in actuality, to meet the probability  
11 numbers, as defined in the high and -- or intermediate  
12 and high consequence events.

13 Could you provide some clarification on  
14 that? Is this meant to truly mean two IROFS that can  
15 independently meet all of the -- so for example, on this  
16 third column on the -- we'll go back to Slide 101, you're  
17 saying if I got rid of IROFS C, IROFS B all on its own  
18 can meet the consequence mitigation and likelihood  
19 reduction all on its own?

20 Or is it okay if we are truly in our ISA  
21 analysis counting on both of those for likelihood  
22 reduction? However, if one fails, we're not going to  
23 call it a basic -- we're not going to have a Part 21  
24 report, because they're both there?

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1 MS. ATACK: Let me try to provide an  
2 answer, and then maybe you can tell me if I understood  
3 your question. We'll do this in an odd manner. If I  
4 understand your question correctly, you're asking if in  
5 the event that both IROFS were needed in order to meet  
6 the performance requirements, and one failed or one had  
7 a deviation, what would be the outcome of the  
8 evaluation, in terms of -- let me just try this, okay.

9 If you have two IROFS that are credited with  
10 -- in order to meet the performance requirements. So  
11 they both provide some sort of a risk reduction. The  
12 only ones that would need to be basic components would  
13 be those in which you need it in order to meet the  
14 performance requirements. So if one of those is  
15 independently capable of meeting the performance  
16 requirements and you have two of those, neither would  
17 be basic components.

18 MR. SLAMA: Okay. I think maybe that's  
19 where my confusion came in, because all right. So in  
20 this scenario that we have here, in this third column  
21 on page 101, in reality what we're saying is one of these  
22 is just a defense in depth. I could really have met my  
23 performance requirements and operated my plant with  
24 IROFS A and B; C doesn't even need to be there?

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1 MS. ATACK: That's true, that's true. In  
2 the far right column, you wouldn't need all of them in  
3 order to comply with the performance requirements. So  
4 one would be designated as an IROFS, and that would --  
5 that would be a defense in depth measure, because if  
6 IROFS B failed, you would still have C, which is capable  
7 of ensuring that you comply with the performance  
8 requirements. Or if IROFS C failed --

9 MR. SLAMA: IROFS C truly could just be  
10 piece of equipment X. It doesn't even have to be called  
11 IROF C. It doesn't have to be an IROFS. It's not an  
12 item relied on safety per se, because it's not required  
13 to meet the performance requirements.

14 MS. ATACK: That would be true.

15 MR. MURRAY: Okay. That's where my  
16 confusion was. I was trying to understand.

17 MS. ATACK: Yeah. I understand what  
18 you're saying, and yeah, and I think I was trying to  
19 address that in the comments section of those boxes,  
20 where it talks about if it's capable of independently  
21 performing that safety function. So you know,  
22 consistent with Scott's comments, I probably should be  
23 very cautious of the terms I use in the slides, because  
24 that, you know, they're subject to interpretation.

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1 MR. SLAMA: Okay.

2 MS. ATACK: Yes. I can address that.

3 MR. SLAMA: Okay, thanks.

4 OPERATOR: No further comments in the  
5 queue.

6 MR. MURRAY: Okay. That brings us to a  
7 break. So shall we take ten minutes? Back at 3:35?  
8 3:35.

9 (Whereupon, the above-entitled matter  
10 went off the record at 3:23 p.m. and resumed at 3:37  
11 p.m.)

12 MS. ATACK: Our numbers are dwindling, but  
13 hopefully everyone's energy level is high. I think  
14 that the commercial grade dedication section will be a  
15 little bit less controversial than the evaluation and  
16 reporting portion, or at least I hope so.

17 So, hopefully we will move more quickly  
18 through this section than we did the previous portion  
19 of the presentation. We'll start with Section A of the  
20 draft regulatory basis, which covers a lack of  
21 regulatory guidance for commercial grade dedication as  
22 it applies to fuel cycle facilities.

23 I'm on Slide 113 now, where we describe the  
24 existing regulatory framework. The current definition

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1 of dedication for nonreactor facilities simply states  
2 that dedication occurs after receipt when that item is  
3 designated for use as a basic component.

4 The NRC has issued a limited amount of  
5 guidance on commercial grade dedication, but the  
6 guidance that has been issued has been more focused on  
7 reactors, which has left a void in the regulatory  
8 framework for dedication as it applies to fuel cycle  
9 facilities.

10 So, the problem as it stands now is that  
11 there's currently no NRC-issued consolidated guidance  
12 for an acceptable form of dedicating commercial grade  
13 items for fuel cycle facilities.

14 As a result, stakeholders don't have the  
15 guidance they need to convey NRC expectations for the  
16 conduct of dedication activities, or to help ensure the  
17 dedication is performed properly.

18 When the staff added Subpart H to Part 70  
19 in 2000, it included requirements for licensees to  
20 implement a system of management measures in the revised  
21 rule, which we discussed previously.

22 For plutonium processing and fuel  
23 fabrication facilities, those licensees were also  
24 required to comply with Appendix B to 10 CFR Part 50.

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1 At the time Subpart H was promulgated, the staff didn't  
2 evaluate the implications of these new requirements to  
3 determine if any conforming changes to Part 21 were  
4 needed.

5 Further, the guidance that is currently  
6 available for dedication is geared towards facilities  
7 that comply with Appendix B to 10 CFR Part 50. So,  
8 there's a need to provide guidance that is directly  
9 applicable and relevant to fuel facilities and that  
10 aligns with our regulatory infrastructure.

11 On Slide 115, I describe the proposed  
12 guidance as being set forth in the regulatory basis. In  
13 order to resolve this regulatory problem, the NRC is  
14 proposing the development of guidance that will clarify  
15 that licensees that are subject to Subpart H of 10 CFR  
16 Part 70 and are not subject to Appendix B of 10 CFR Part  
17 50 may satisfy the requirements of commercial grade  
18 dedication by implementing their existing management  
19 measures programs under 10 CFR Part 70.

20 It is the staff's position that the  
21 implementation of these management measures programs  
22 ensures the availability and reliability of IROFS at  
23 fuel cycle facilities for the purposes of design,  
24 procurement, installation and maintenance.

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1           Then NRC reviews and approves licensee  
2 management measures programs as part of the safety  
3 program required under 70.62, and we ensure the  
4 effective implementation of those measures through  
5 routine inspections.

6           For fuel cycle facilities regulated under  
7 Subpart H, and subject to the requirements of Appendix  
8 B to 10 CFR Part 50, those would be the plutonium  
9 processing facilities, the proposed rule changes  
10 described in the regulatory basis will clarify the  
11 applicability of Appendix B QA controls to the  
12 dedication process, and we'll discuss those changes in  
13 subsequent slides.

14           Section B would be those subsequent slides.  
15 So, before we move onto that, does anyone have questions  
16 on Section A? Anyone in the room? Anyone on the phone?

17           OPERATOR: Star 1, and record your name and  
18 affiliation.

19           MS. ATACK: Hearing none, I'll move onto  
20 Section B, since Sections A and B do have a high degree  
21 of interrelations. So, if you didn't have an  
22 opportunity to ask a question on Section A, you might  
23 think of something as we go through Section B.

24           Section B covers the proper place for

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1 dedication requirements. The existing regulatory  
2 framework, as we previously noted, lies in the  
3 definition of dedication in the current rule, and that  
4 -- excuse me, that definition is very simplistic.  
5 Again, it just states the dedication occurs after  
6 receipt when that item is designated for use as a basic  
7 component.

8 I'm sure you can acknowledge that there  
9 would be a large degree of variation in how licensees  
10 may interpret those words.

11 On Slide 118, we identify that the problem  
12 with the way the regulation is currently written is that  
13 not only is the definition lacking in detail as it  
14 applies to fuel cycle facilities, but it is generally  
15 poor practice for regulatory requirements to reside  
16 solely within the definitions. I think a lot of the  
17 discussion we've had within today's meeting identifies  
18 the need to promulgate separate requirements that will  
19 describe the expectations for commercial grade  
20 dedication, and Section B as it applies to fuel cycle  
21 facilities does acknowledge that as well.

22 So, going to Slide 119, we discussed the  
23 proposed changes to the regulations, and again this  
24 slide is two fold because part of the solution that we've

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1 recommended is guidance for those facilities that are  
2 not subject to Appendix B, which we discussed in the  
3 previous section, and in this area we proposed changes  
4 to the regulations to acknowledge that those facilities  
5 that are subject to Appendix B as part of their licensing  
6 basis do have separate expectations than those who are  
7 not subject to Appendix B.

8 So, for the fuel cycle facilities that are  
9 subject to the requirement of Subpart H and Appendix B,  
10 the newly developed Section 2171 of the rule would  
11 apply.

12 Those facilities will also be expected to  
13 perform commercial grade dedication in accordance with  
14 their Appendix B QA programs.

15 As we stated previously, guidance  
16 discussed in Section A of the draft regulatory basis  
17 would be applied to communicate the link between  
18 management measures programs and performance of  
19 commercial grade dedication for those facilities that  
20 are not subject to Appendix B.

21 Do we have any questions on that section?  
22 Any questions on the phone?

23 OPERATOR: We have two. First, Nancy Parr  
24 from Westinghouse.

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1 MS. PARR: Sabrina, one thing that  
2 concerns me about this is it seems like we're starting  
3 to mix and match management measures and the 18 criteria  
4 with Appendix B, and what we've found within our own  
5 company is that people generally understand Appendix B  
6 and then they frequently have a hard time understanding  
7 quality assurance being different in terms of  
8 management measures for Part 70 regulated facilities.

9 So, my concern is with mixing and matching  
10 of requirements can really cause a lot of future  
11 confusion when new people who haven't been involved in  
12 this come in with their own perspectives and  
13 interpretations.

14 So, it does confuse me, but why would a  
15 facility have to comply with management measures and  
16 Appendix B? Because in being involved in Part 70  
17 Subpart H rulemaking, there was a lot of discussion that  
18 management measures was a lower tier, if you will,  
19 quality assurance program for fuel cycle facilities  
20 that didn't have the same risk as, say, a power reactor.

21 So, it seems redundant and confusing for a  
22 facility to have to comply with both. And some of the  
23 proposed rulemaking seems to stem towards addressing  
24 the problems caused by the facilities having a

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1 management measures program and an Appendix B, and some  
2 of the exemption requests that they have issued.

3 So, again, maybe just another  
4 philosophical question but I don't understand what  
5 value you get from having a management measures program  
6 and an Appendix B program.

7 MS. ATACK: Thank you for the comment,  
8 Nancy, and I think the intent of the message I was trying  
9 to communicate is that for those licensees who have a  
10 commitment to comply with Appendix B either as part of  
11 their regulatory requirements under Part 70, which  
12 would be the plutonium processing facilities, which is  
13 limited to MOX, or those that have committed to comply  
14 with Appendix B, those would be the only facilities  
15 where we're providing the more prescriptive dedication  
16 requirements.

17 It is not intended to make the rule overly  
18 prescriptive or complex. The intent is to separate out  
19 those facilities that have more rigorous quality  
20 assurance requirement from those that have the  
21 expectation simply for a management measures program.

22 So, I don't think the staff has any  
23 expectation that licensees would have both a management  
24 measures program and an Appendix B program, and we would

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1 use that as input into the way they do commercial grade  
2 dedication.

3 It is intended to be very simplistic, such  
4 that the rule directs facilities that have a licensing  
5 basis that directs them to comply with Appendix B to  
6 perform dedication in accordance with Appendix B, and  
7 they would also be subject to 21.71, whereas the  
8 facilities that don't have to comply with Appendix B  
9 would essentially complete commercial grade dedication  
10 as part of implementing their management measures  
11 programs.

12 So, that would essentially mean that you  
13 procure an item. You might do some sort of receiving  
14 process. But for fuel cycle facilities, there's a  
15 large degree of functional testing or post-installation  
16 testing involved as part of the receiving process.

17 So, my perception of how we would probably  
18 proceed with guidance is that an item would be a basic  
19 component after the completion of those  
20 post-installation tests when you've actually verified  
21 that it will perform its safety function. Does that  
22 help to answer your question or concern?

23 MS. PARR: It does, but this will probably  
24 come when we do the cost estimates as well. But using

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1 the same terminology and saying commercial grade  
2 dedication for, say, an Appendix B Program and then  
3 having slightly different criteria for commercial grade  
4 dedication for a Part 70 facility without an Appendix  
5 B Program really adds complexity to your Level 2 QA  
6 procedures and those management systems and policies.

7 MS. ATACK: I think I'm failing to  
8 appreciate your concern, Nancy. Maybe I'm  
9 oversimplifying the situation. So, maybe you can help  
10 me understand it better.

11 The intent of what the staff is attempting  
12 to do through the rulemaking and the guidance would be  
13 to separate out the fuel cycle facilities such that  
14 those that comply with Appendix B as part of their  
15 licensing basis perform dedication the same way that  
16 reactor facilities do, and that's consistent with the  
17 way that the licensees are implementing it right now.  
18 And those facilities and activities that don't have  
19 Appendix B as part of their licensing basis would  
20 essentially continue to perform activities as they do  
21 now.

22 We would acknowledge that the performance  
23 of those management measures processes satisfy the  
24 intent of commercial grade dedication.

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1 MS. PARR: And this difficulty comes from  
2 being a Part 70 facility without an Appendix B program  
3 on management measures activities are controlled, say,  
4 at a local level. And we do have a company-wide driven  
5 Part 21 program which we would use if we had to evaluate  
6 whether a substantial safety hazard could have  
7 occurred.

8 But when this company-wide Part 21 program  
9 is really the processes that evolve from it in the  
10 commercial grade dedication procedures are fairly  
11 complex for dealing with Appendix B and our product  
12 quality requirements. But they have typically left,  
13 say, the management measures aspects, they don't even  
14 deal with that. That's dealt through our license  
15 application and our local procedures at the license  
16 site.

17 I do believe that some of these proposed  
18 changes will further complicate our product quality  
19 processes and procedures.

20 MS. ATACK: Thank you for the comment,  
21 Nancy. Perhaps in future dialogues we can get into some  
22 more specific details so that I can understand your  
23 concern a little bit better and I can help inform our  
24 guidance as we get into that stage where we're working

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1 to prepare guidance so I'm prepared to address your  
2 concern. Because right now, I don't feel like I have  
3 a firm grasp on the concern.

4 MS. PARR: That's great. We will take it  
5 offline, and talk in greater detail.

6 MS. ATACK: Thank you, Nancy.

7 OPERATOR: Next up is Bob Link of Areva.

8 MR. LINK: Thank you. This is more of a  
9 clarifying question. And I appreciate, Sabrina, your  
10 I guess willingness to acknowledge the management  
11 measures programs we have in place, and the -- while it's  
12 a difficulty in terms of what I would characterize as  
13 an Appendix B full blown dedication process.

14 But that being said, I want to make sure  
15 your words and your expectations match my  
16 interpretation of your words and that is if I apply, as  
17 I must apply via my licensing commitment, the management  
18 measures that are outlined in our license application,  
19 no further effort or activities would be necessary to  
20 dedicate a basic component other than what we discussed  
21 before in terms of the logic evaluation to identify  
22 those basic -- those items under your scenario in the  
23 IROFS scenario description.

24 We'd have to do that, but then as we acquire

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1 items, catalog items or commercial items, whatever you  
2 want to call them, they, by the nature of our management  
3 measures process would then be anointed following our  
4 full receipt testing qualification requirements as  
5 represented.

6 In other words, and I -- I guess to be very  
7 frank about it, you would not expect to see a separate  
8 analysis per item that would identify all the critical  
9 characteristics and explicitly look at how we assure  
10 that those critical characteristics are fulfilled.

11 MS. ATACK: That is correct.

12 MR. LINK: Okay.

13 MS. ATACK: I think what we would seek to  
14 outline in guidance is the way that the management  
15 measures program satisfies the commercial grade  
16 dedication process and also I think one of the critical  
17 elements will be identifying when that item is  
18 designated for use as a basic component because of the  
19 large degree of functional testing and other processes  
20 that come into play before fuel cycle facility licensees  
21 are ready to declare that as a basic component.

22 I think that will be an area that we need  
23 to pay special attention to in order to make sure that  
24 we arrive at the right level of guidance that will

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1 provide clear expectations for when an item becomes a  
2 basic component.

3 MR. LINK: Okay, thank you.

4 MS. ATACK: Your question made me think of  
5 another note I wanted to make, Bob. Thank you for that.  
6 This one applies to the Appendix B facilities, and I just  
7 want to note because we have approved some graded  
8 quality assurance programs.

9 So, for those Appendix B facilities that do  
10 have existing graded provisions provided as part of  
11 their licensing basis, those would continue to be valid.  
12 And in the event that any Part 21 rulemaking element  
13 would be more prescriptive than something that the staff  
14 had already approved as part of the licensing basis for  
15 a facility, then the licensee would continue to comply  
16 with those license basis commitments that the staff  
17 approved via safety evaluation report.

18 Do we have a question in the room?

19 MR. NICHOL: Mark Nichol, NEI. I  
20 apologize. Just for my own benefit to understand how  
21 these definitions and rules are applied to fuel cycle  
22 facilities: I'm trying to understand if a fuel cycle  
23 facility goes out to procure something, and let's just  
24 say this something could meet the definition of a basic

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1 component, it -- or it could result in a substantial  
2 safety hazard if there were a defect.

3 So, if the fuel cycle facility is going out  
4 to procure this, is it always procured as commercial  
5 grade items that always are procured as a basic  
6 component? Could it be one or the other, depending on  
7 whether management measures were applied during the  
8 procurement process.

9 And I'm wondering because I don't really  
10 understand where that distinction lies. So, I'm  
11 wondering what the NRC's position is on that.

12 MS. ATACK: Well, I think it is more of a  
13 licensee position. I don't think we really determine  
14 how licensees procure things. What I've seen as part  
15 of our site visits and part of familiarity with some of  
16 our sites that are under construction and operating is  
17 it would be separate for the facilities to comply with  
18 Appendix B versus those that have management measures  
19 programs.

20 So, typically the Appendix B facilities  
21 would be procuring many items as basic components with  
22 qualified suppliers. The facilities that aren't  
23 required to comply with Appendix B would be doing much  
24 more of commercial grade dedication type approach by

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1 implementing their management measures programs.

2 So, Bob Link may be able to speak to this  
3 because we visited his site, and he is very familiar with  
4 the ability of licensees to apply a graded process to  
5 their procurement as part of their management measures  
6 programs.

7 So, for instance, the Areva facility in  
8 Richmond. We saw a sliding scale depending on the  
9 safety significance and complexity of the items that are  
10 being procured. Whereas for the more safety-significant  
11 or complex items, it would be very close to an Appendix  
12 B type of procurement without necessarily invoking  
13 Appendix B in the procurement document. There may be  
14 some procurement requirements to invoke industry  
15 standards for more complex and safety significant  
16 items.

17 For other items such as plastic pails,  
18 which is a very common example we use for fuel cycle  
19 facilities, i.e. one that would hold UO2, those pails  
20 would be procured commercially and then it would be a  
21 simple kick and count and making sure that they don't  
22 exceed the volume that they are supposed to hold, and  
23 make sure that they're made out of the material that you  
24 would expect just by a visual type of examination.

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1           So, for the non-Appendix B facilities,  
2           there's a sliding scale in terms of how they procure  
3           things, but I've seen very few things that I would deem  
4           as being procured as a basic component. I would say  
5           mostly all of them are procured as a commercial grade  
6           item, and the licensees' processes are what make it a  
7           basic component.

8           MR. SCHILTHELM: So, listening to that  
9           discussion and thinking back earlier to the discussion  
10          about changing the rule such that when you invoke Part  
11          21 you also must invoke Appendix B. I think that was  
12          on one of the earlier rule changes. You might want to  
13          think about how that requirement would need to be  
14          tailored a little bit for a fuel facility who could  
15          invoke Part 21 but wouldn't necessarily be invoking  
16          Appendix B on the supplier. If I understood that  
17          previous discussion.

18          You could buy a -- you could invoke Part 21  
19          on a supplier as a fuel cycle facility without invoking  
20          Appendix B. I believe.

21          MS. ATACK: You could. I don't know that  
22          we've seen that happen because what would need to happen  
23          in order for that to occur would be you would invoke Part  
24          21 and a management measures program, which I've not

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1       seen occur.

2                   It is possible. I think if I recall  
3 correctly, maybe the discussion we had earlier was  
4 geared toward invoking Appendix B as part of  
5 procurements for basic components in which case I think  
6 we have addressed that in the guidance and the proposed  
7 rule changes such that the only fuel cycle facilities  
8 that would be required to comply with those Appendix B  
9 program elements would be those that are already subject  
10 to Appendix B.

11                   Does that address your -- I understand what  
12 you're saying. I don't know if we said that earlier or  
13 not in terms of invoking Part 21 in the purchase order,  
14 but if we did we will make sure to take a close look at  
15 that because there is the potential that you would  
16 invoke Part 21 but not Appendix B. Probably a remote  
17 possibility, but it's possible.

18                   Do we have other questions or comments on  
19 the phone?

20                   OPERATOR: One from Scott Murray of Global  
21 Nuclear Fuel. Your line is open.

22                   MR. MURRAY: Sabrina, I'm -- I want a  
23 clarification. I'm looking at slide 119, please. In  
24 the center section of that slide, it talks about

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1 guidance discussed in Section A of the draft regulatory  
2 basis. I'm having a little difficulty finding  
3 specifically Section A. Can you help me find where that  
4 description is?

5 MS. ATACK: That would be the first subject  
6 under commercial grade dedication in the regulatory  
7 basis. Those were the slides that we discussed in the  
8 beginning of this segment of the presentation. Let me  
9 see if I can find the page.

10 MR. MURRAY: So, it is actually chapter 3?

11 MS. ATACK: Right, chapter 3.

12 MR. MURRAY: Okay, page 52?

13 MS. ATACK: Regulatory guidance on page  
14 52.

15 MR. MURRAY: Yes, it wasn't obvious when  
16 you said Section A. I couldn't figure out specifically  
17 if you were talking about the commercial grade  
18 dedication chapter.

19 MS. ATACK: Right. In that, Section A  
20 does apply to all of the facilities that we're talking  
21 about as part of the rulemaking and guidance  
22 clarification. So, the lack of regulatory guidance is  
23 an issue for more than just -- more than just the fuel  
24 cycle facilities. So, that's probably why it is a

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1 little bit harder to find that one.

2 MR. MURRAY: Yes, but specifically I think  
3 what I'm asking about is for that first bullet fuel cycle  
4 facilities subject to Subpart H but not subject to  
5 Appendix B, and I think the paragraph or paragraphs that  
6 you're suggesting are at the top of page 54. I'm just  
7 trying to get clarification that I'm reading the right  
8 thing here.

9 MS. ATACK: On page 54, we talk about both  
10 of the situations and the proposed changes to the  
11 regulations. We talk about how the fuel cycle  
12 facilities that are regulated under Subpart H, except  
13 those that are required to comply with Appendix B,  
14 perform management measures. We don't recommend any  
15 [rule] changes for those facilities.

16 Then down in guidance, we talk about the  
17 guidance that we plan to provide, and it goes on in a  
18 bit of detail as to what the staff believes we will  
19 provide as part of the guidance. It goes into 55 as  
20 well.

21 MR. MURRAY: Okay, well, the only other  
22 comment I would make is I hope everybody knows that  
23 typically management measures when they're applied to  
24 these types of procured items happen when they're put

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1 into service, when they're installed. They don't  
2 always happen when they are procured or received. They  
3 happen -- the functional testing and other things as  
4 these component items is obviously placed into service.

5 So, I don't know if that was obvious  
6 throughout the whole document, but that's just one point  
7 I'm trying to make.

8 MS. ATACK: Thanks, Scott. I've  
9 mentioned that a couple of times verbally but as we move  
10 into the guidance preparation that will be something  
11 that will be very important to make sure we continue to  
12 emphasize is that the functional testing and the in  
13 service performance are a big part of the dedication  
14 process.

15 MR. MURRAY: It's a little different in I  
16 think the true definition of dedication in this sense.  
17 And the other point is some of these components that can  
18 be IROFS for different accident sequences may or may not  
19 be a basic component in that particular accident  
20 sequence.

21 In other words, the same thermocouple when  
22 applied over here may not be a basic component, but when  
23 it's applied over there because there's other controls  
24 or other reasons, it is a basic component. So, that's

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1           why it is important to understand that the management  
2           measures, if they're being used in lieu of dedication,  
3           would not necessarily be the same even though they're  
4           both IROFS in two different places.

5                         One place it might be a basic component.  
6           In another place it may not.

7                         MS. ATACK:  Very true.  Thank you for that  
8           comment, Scott.

9                         MR. MURRAY:  Thank you.

10                        MS. ATACK:  Any other --

11                        OPERATOR:  No further comments.

12                        MS. ATACK:  Okay, great.  So, let's move  
13           onto Section E, which is the definition of commercial  
14           grade item.  This is probably the only part of the  
15           proposed rulemaking that the fuel facilities are  
16           genuinely happy about.  So, I'm pleased to speak about  
17           this set of slides.

18                        On slide 121, we cover the existing  
19           regulatory framework, and what you find in the  
20           definition of commercial grade item that's provided in  
21           the current version of Part 21 that is in use right now  
22           is that it's very prescriptive.

23                        Commercial grade item for facilities other  
24           than nuclear power plants includes a lot of

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1 requirements. The item is not subject to design or  
2 specification requirements that are unique to those  
3 facilities or activities. The item has to be used in  
4 applications other than those facilities or activities,  
5 and the item has to be able to be ordered from the  
6 manufacturer or supplier on the basis of pre-existing  
7 specifications.

8 So, in order to find a commercial grade item  
9 for fuel cycle facilities, it has to be something very  
10 straightforward that you can do a Google search and  
11 order from a supplier. They've already got to be making  
12 this for multiple users, and it can be overly confining  
13 for fuel cycle facilities, which, as we've already  
14 discussed, have very specific needs in terms of some of  
15 the items procured for their facilities due to their  
16 unique nature.

17 The regulatory problem, which I kind of let  
18 the cat out of the bag, is that the definition is very  
19 prescriptive as currently written. The commercial  
20 grade item definition that is in use right now restricts  
21 commercial grade items to those that are generic in  
22 nature, and fuel cycle facilities have had some  
23 difficulty in finding components that can be dedicated  
24 as commercial grade items due to the specific needs of

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1 the facility.

2 Having such a limited definition of what  
3 can be deemed a commercial grade item has resulted in  
4 procurement challenges and the need for licensees to  
5 seek the exemption requests that have been mentioned  
6 previously during the presentation.

7 So, the proposed change to the regulations  
8 is changing the definition, and this was discussed  
9 during the morning session. The proposed definition  
10 the staff is providing would be simply that a commercial  
11 grade item is an item that is not a basic component.  
12 That would relieve all the prescriptiveness as to what  
13 can be dedicated as a commercial grade item.

14 That would allow items that are specific to  
15 facilities and users to be dedicated. That's the end  
16 of that section. Any questions on commercial grade  
17 item proposed changes?

18 I see none in the room. Do we have any on  
19 the phone?

20 OPERATOR: Robert Link from Areva, your  
21 line is open.

22 MR. LINK: Actually, I had a clarification  
23 question on the previous section, and then I have one  
24 on this one too. But apparently I prompted you to think

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1 about some additional information not in the slides  
2 relative to -- and I think specifically you were  
3 speaking to those facilities that have already Appendix  
4 B programs, fuel cycle facilities and have some license  
5 commitments in that context.

6 I'm going to use the words you would expect  
7 under the proposed methods going forward. They would  
8 be - and I'll use the word grandfathered - in, under  
9 their existing commitments and requirements, and the  
10 new rule would not necessarily have to be proscriptively  
11 fulfilled.

12 MS. ATACK: I'm not sure if that's entirely  
13 accurate. The existing licensees who have certain  
14 provisions approved via safety evaluation report would  
15 continue to comply with the provisions of those  
16 approvals.

17 They would be subject to the new  
18 requirements in 21.71. So, I would expect from what  
19 I've seen in the amendment request would be that most  
20 of the provisions of 21.71 would apply, but where 21.71  
21 is more prescriptive than something we've already  
22 approved, the licensees would default to that less  
23 prescriptive approval.

24 So, it is not that they will be using an

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1 entirely separate set of requirements. It will be that  
2 they're complying with 2171 and where 2171 is more  
3 prescriptive than something we've already approved,  
4 then they would default to that less prescriptive  
5 requirement.

6 What I've seen would -- example would refer  
7 to the way that the technical evaluation performed as  
8 part of dedication is documented. So, that could be  
9 documented as part of a procurement package instead of  
10 in a separate technical evaluation for certain items.  
11 Examples like that.

12 So, they would be a little bit more specific  
13 in terms of what changes would be applicable to  
14 facilities that comply with Appendix B. Yes, there  
15 would be some cases where they wouldn't have to comply  
16 with the new provisions because they are grandfathered  
17 in, per se, because of existing approvals.

18 MR. LINK: Okay, I think that makes sense  
19 to me. There might be a scenario I'd perceive that a  
20 licensee that has those type of exemptions may review  
21 the outcome of the rulemaking process and choose to  
22 basically come in and say, "I don't need my exemption  
23 anymore."

24 MS. ATACK: That's possible. I think this

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1 would be -- and there was also a comment from the  
2 audience while you were talking. I think this is  
3 probably something we would want to address as part of  
4 the statement of considerations with the rule to make  
5 it clear what is applicable.

6 But yes, if a licensee would prefer to  
7 comply with the rule as revised, they could at any time  
8 come to the NRC and say, "I no longer want this license  
9 exemption that has been approved or this condition, and  
10 I'm going to make a change to my program to bring it into  
11 line with the new provisions of the rule."

12 MR. LINK: Now I guess I want to move onto  
13 the last topic and maybe use an example just to make sure  
14 I'm completely understanding it.

15 I admit that the existing -- I guess  
16 interpretation would not allow -- and I'm going to use  
17 a pencil tank. As you know, we use geometry controls  
18 in terms of -- and as a passive IROFS in limiting the  
19 diameter of a tank to a safe geometry.

20 Yet that would not necessarily be a catalog  
21 item, and we would write a purchase specification to  
22 assure that obviously both materials are compatible  
23 with the environment to work in as well as in the context  
24 of the criticality issue to be of safe geometry and

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1 diameter.

2 That's not a catalog item, per se, and under  
3 the -- I guess one person's interpretation of the  
4 existing rule, we couldn't commercially dedicate that.  
5 And you're saying that under your proposal, if it comes  
6 true, that could become a commercial grade item which  
7 we could dedicate, and then once we've satisfied all our  
8 management measures, then classify it as a basic  
9 component.

10 MS. ATACK: That is correct. You can give  
11 the next presentation, Bob. You've mastered it.  
12 Okay, do we have any other questions on that section?  
13 All right, that brings us to the final section of my  
14 presentation, which is Section G: the Clarification of  
15 Quality Assurance requirements for the conduct of  
16 Dedication for Facilities that are Subject to Appendix  
17 B.

18 I think we've already actually touched on  
19 this. So, I'll pace ourselves through it. The  
20 existing regulatory framework in the current definition  
21 of dedication as applied to power reactor licensees does  
22 include the requirement that the dedication process be  
23 conducted in accordance with Appendix B to 10 CFR Part  
24 50.

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1           However, there are no similar requirements  
2           to identify QA requirements applicable to dedication  
3           activities to other facilities that are subject to the  
4           requirements of Part 21.

5           So, that brings us to the regulatory  
6           problem: That the regulation as currently written  
7           doesn't provide a description within Part 21 or any  
8           associated guidance related to Part 21 to describe the  
9           QA controls that should be applied to dedication  
10          activities for nonreactor facilities.

11          Moving onto Slide 126, the proposed changes  
12          that the staff has recommended would be first for fuel  
13          cycle facilities regulated under Subpart H, and not  
14          subject to the requirements of Appendix B. We wouldn't  
15          make any changes to the rule.

16          The guidance that we already discussed  
17          previously would describe the link between management  
18          measures and dedication. However, for the fuel cycle  
19          facilities that are regulated under Subpart H and do  
20          have to comply with Appendix B to 10 CFR Part 50, those  
21          facilities as part of proposed rule changes would need  
22          to comply with Appendix B for their dedication  
23          activities.

24          That is the end of my presentation. Do we

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1 have questions on the applicability of Appendix B for  
2 dedication for fuel cycle facilities? None in the  
3 room. Do we have any on the phone? That concludes my  
4 remarks. I believe that concludes our meeting, but  
5 I'll hand it over to our facilitator to wrap up.

6 MS. CLARK: I just want to thank everybody.  
7 We have had a very extensive and robust discussion  
8 today, and I can assure you that your comments and  
9 questions will help the staff as we move forward in  
10 evaluating our regulatory analysis for Part 21.

11 The transcript for this meeting will be  
12 posted on our website, and I think that concludes the  
13 meeting. Anything else? All right, thank you very  
14 much.

15 MR. HEATH: I just want to thank everybody  
16 that showed up today, and for those that are still on  
17 the phone. Again, my name is Jermaine Heath, and I'm  
18 leading the -- or project managing the rulemaking effort  
19 altogether.

20 So, if you have questions or comments, you  
21 can email me. You should have my information. I  
22 encourage you to subscribe to the Part 21 website if you  
23 haven't already. I don't know if it's on here.

24 If you just go to Google. Go to Google and

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1 type in NRC vendor into the Google search box. The  
2 instructions are on the slide. You'll find a link to  
3 10 CFR Part 21. When you pull up our website, they'll  
4 take you there, and then you'll see a page at the top,  
5 "Subscribe to updates."

6 Then anything we issue that is Part 21  
7 related you'll get automatically, in addition to it just  
8 being put on our website. It'll come right to your  
9 inbox. So, my information is there on the slides. If  
10 you have any questions related to Part 21 or this  
11 meeting, get them to me. If I can't answer your  
12 questions between me and my colleagues, I'll find the  
13 right people.

14 I appreciate you coming. So, if you didn't  
15 get your questions answered, again the meeting is being  
16 transcribed. So, when that comes in, the staff will  
17 take time to go through all of the meeting questions and  
18 comments and we'll take those into consideration as we  
19 prepare the final reg basis, which we hope to go out some  
20 time in June.

21 So, thanks again for coming. Thank you.  
22 That concludes our meeting, Operator.

23 (Whereupon, the above-entitled matter went  
24 off the record at 4:18 p.m.)

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