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Title: 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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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

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TUESDAY

APRIL 28, 2015

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ROCKVILLE, MARYLAND

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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

KATI AUSTGEN, NEI

SIDNEY BERNSEN *

THOMAS BIAGI, Parker Hannifin*

ALAN BLAMEY, Region 2 Division of Fuel Facility Inspection*

KEVIN BONSER, General Atomics *

DAVID BREEDING *

WILLIAM BRYAN, Ansys Inc *

BARRY BRYANT, Dominion *

ROBERT BURG, Engineering Planning & Managing *

LARRY CARSON, C&D Technologies *

STEPHEN CASADEVALL, ASCO Valve *

CURTIS CASTELL, Chicago Bridge & Iron

ANN COTTINGHAM, Nuclear Energy Institute *

STEVEN DIMAURO, C&D Technologies *

PAUL DUKE, PSEG *

MICHAEL DUNKELBERGER, MPR

PAUL GARCIA, Ariba Inc *

DEWEY GODFREY, Centrus Energy Corp *

LESLIE GRAY, Erin Engineering *

JIM GRESHAM, Westinghouse Electric Company

BRENDA GRIEGO, ALion Science & Technology *

STANLEY GRIFFIN, GE Hitachi Nuclear Energy *

MICHELE GUTMAN, Westinghouse Electric Co *

BRYAN HALL, NSL Analytical *

JESSICA HANEK, Sargent Lundy LLC *

JOSHUA HART, Stevenson & Associates *

JERMAINE HEATH, NRO/DCIP

KEN HEFFNER, Certrec Corporation *

BILL HORIN, Winston & Strawn

VICTORIA HUCKABAY, NRO/DCIP

KERRI KAVANAGH, NRC *

AL LAFLEUR, NextEra Energy *

MIKE LEAHY, Exelon Corporation *

DANIEL LEWTON, Westinghouse Electric Co *

ROBERT LINK, Areva, Inc.*

RUSSELL LION, L&S Machine Co *

TOM LOOMIS, Exelon Corporation

JON LUBAHN, Consumers Energy *

ROBERT MARSHALL, NuScale Power *

HERBERT MAYES, Southern Company *

ADAM MCCARTNEY, Cameron *

ZINA MCDOWELL HEATH, AECOM *

SCOTT MURRAY, Global Nuclear Fuels *

MARC NICHOL, NEI

MICHELLE NYZIO, Lockheed Martin *

PATRICK OLSON, Twin City Fan Companies *

NANCY PARR, Westinghouse Electric Company *

PAUL PRESCOTT, NRO/DCIP

PEGGY RESCHESKE, Southern California Edison Company*

WILLIAM ROGERS, Lockheed Martin *

JOHN ROGGE, NRC Region 1 Div of Reactor Safety *

FINDLAY SALTER, SCE&G

STEVE SCHILTHELM, B&W

NICK SERAFIN, Consumers Energy Laboratory Services *

MARCY SHOPE, Nuclear Field Services Inc *

JOHN SIMMONS, Luminant Power *

CARLOS SISCO, Winston and Strawn LLP *

CHARLES SLAMA, Urenco *

TIMOTHY SNOKE, General Atomics *

GLENN STRAUSSER, USEC *

WILLIAM STUCKEY, AECOM *

MARYANN SWIERGOL, Hamill Manufacturing Company *

JOSEPH TAPIA, Mitsubishi Nuclear Energy Systems *

GEORGE TARTAL, NRC

WILLIAM WARE, Southern Nuclear Operating Company

DOUG WEAVER, Westinghouse Electric Company

FRED WILLIS, Southern Nuclear Operating Company

DOUG YATES, MOX Services

GAYLE ELLIOTT, AREVA Inc.

JANA BERGMAN, CW/Scientech

ROBERT THEURET, Westinghouse Electric Company

AIXA BELEN, NRC

TONI SAKADALES, NRC

STEVE TOELLE, Centrus Energy Corp.

JIM ROWLANDS, Precision Custom Components

NIMA ASKEBONSSI, NEI

PATRICIA CAMPBELL, GEH

M. VANN MITCHELL, MHI

THOMAS MATULA, NRC

ANDREA KEIM, NRC

ASHLEY THOMAS, NRC

ANDREA VALENTIN, NRC

* present by telephone

T-A-B-L-E O-F C-O-N-T-E-N-T-S

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

(9:04 a.m.)

MS. CLARK: Morning, everybody. Can everybody hear me okay?

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

OPERATOR: You are now live.

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

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

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

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

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

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

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

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

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

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

Our meeting is going to be divided into two

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. HUCKABAY: Water.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Operator?

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

MR. HEATH: Yes.

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

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

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

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

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

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

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

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

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

regulatory position. So, thank you.

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

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

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

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

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

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

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

MR. HEATH: Okay.

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

MR. HEATH: Does that answer your question?

(No audible response.)

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

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

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

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

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

(Technical difficulties.)

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

MR. HEATH: Repeat that?

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

MR. HEATH: Okay.

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

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

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

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

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

MR. HEATH: Go ahead, Marc.

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

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

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

MR. HEATH: Thank you, Marc.

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

MR. PRESCOTT: And again, the staff

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

MR. HEATH: Any other questions from the audience?

(No response.)

MR. HEATH: Okay. Operator?

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

Your line is open.

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

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

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

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

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

MR. HEFFNER: G, golf.

MR. HEATH: Oh, golf? Okay.

MR. HEFFNER: Yes. Golf, yes.

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

MR. HEFFNER: Okay. Thank you.

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

Your line is open.

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

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

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

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

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

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

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

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

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

MR. LINK: Thank you.

MR. HEATH: Yes.

OPERATOR: No further questions from the phone.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. HEATH: Yes. Tom --

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

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

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

MR. HEATH: Operator, is he okay?

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

MR. LOOMIS: Okay. Now?

OPERATOR: Move closer, please.

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

OPERATOR: Let's try.

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

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

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

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

your concern.

MR. LOOMIS: Right.

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

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

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

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

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

PARTICIPANT: Of the procurement document.

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

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

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

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

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

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

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

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

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

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

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

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

MR. HEATH: I think that's fair.

Yes?

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

MR. HEATH: That would be correct, yes.

MR. DUNKELBERGER: Okay. Thank you.

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

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

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

MR. HEATH: Thank you.

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

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

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

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

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

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

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

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

MR. CASTELL: Okay. Thanks.

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

MR. PRESCOTT: Yes, sir.

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

MR. PRESCOTT: Okay.

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

MR. PRESCOTT: Okay.

MR. LOOMIS: I mean, we deal with

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

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

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

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

PARTICIPANT: We'll keep you awake.

(Laughter.)

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

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

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

(No audible response.)

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

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

OPERATOR: All right. We have Adam McCartney. You line is open.

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

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

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

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

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

MR. HEATH: Thank you.

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

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

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

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

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

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

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

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

OPERATOR: You were fading in and out.

MR. HEATH: Operator, can you hear me?

OPERATOR: Loud and clear.

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

OPERATOR: Also loud and clear.

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

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

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

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

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

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

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

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

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

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

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

(No response.)

MR. HEATH: Operator, phone?

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

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

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

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

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

MR. HEATH: Can you hear me?

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

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

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

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

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

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

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

OPERATOR: Mr. Bernsen, any further comment?

MR. BERNSEN: No.

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

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

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

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

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

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

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

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

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

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

End of Section 6. Any questions from the audience?

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

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

MR. HEATH: Thank you, Marc.

More questions or comment from the audience?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. CLARK: Operator, could you hear that?

OPERATOR: Loud and clear.

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

MR. WILLIS: Based on what you said,

Paul --

MR. PRESCOTT: Yes.

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

MR. PRESCOTT: Okay.

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

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

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

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

OPERATOR: Operator here.

MR. HEATH: We have anyone on the phone?

OPERATOR: We have four questions from the phone.

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

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

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

OPERATOR: Copy that.

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

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

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

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

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

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

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

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

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

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

However, the intent of that rule amendment

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

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

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

Operator, please stand by.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

section. Are those questions no longer takeable?

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

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

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

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

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

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

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

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

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

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

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

MS. ATACK: Okay. Yeah. For -

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

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

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

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

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

21.40 it seems like that verbiage -

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

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

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

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

MR. HEFFNER: Thank you.

MR. PRESCOTT: Yup.

OPERATOR: No further questions or comments from the phone.

MS. HUCKABAY: All right. Thank you.

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

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

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

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

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

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

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

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

On Slide 57 we're describing those changes

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

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

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

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

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

MS. HUCKABAY: Thank you.

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

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

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

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

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

will take that back for consideration of the exact interpretation.

MR. CASTELL: Okay. Thank you.

MR. PRESCOTT: Thank you.

MS. HUCKABAY: Thank you.

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

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

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

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

OPERATOR: No questions or comments on the

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

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

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

MS. HUCKABAY: Thank you.

OPERATOR: No further questions or comments from the phone.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

just try to get that crystal clear.

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

OPERATOR: No further questions or comments from the queue.

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

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

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

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

top-tier vendors.

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

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

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

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

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

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

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

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

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

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

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

MS. CLARK: Oh, I'm sorry.

MR. PRESCOTT: - under the current conditions.

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

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

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

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

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

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

MR. PRESCOTT: Thank you.

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

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

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

MR. DUNKELBERGER: Oh, 14-05.

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

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

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

MR. PRESCOTT: Okay.

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

MR. PRESCOTT: Right. Thank you, Mike.

MR. LOOMIS: Hi, Paul.

MR. PRESCOTT: Hi, Tom.

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

MR. HEATH: Where is that, Tom?

MR. LOOMIS: On 21.7 on exemptions on Page

106 in the reg basis.

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

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

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

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

situation.

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

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

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

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

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

you.

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

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

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

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

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

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

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

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

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

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

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

MR. SLAMA: Okay. Thank you.

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

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

is very important for that clarity.

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

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

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

OPERATOR: No further questions or comments from the phone.

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

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

from a basic component.

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

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

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

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

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

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

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

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

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

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

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

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

MR. NICHOL: Marc Nichol, NEI. Just a

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

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

MR. PRESCOTT: Yes. Yes.

MR. NICHOL: Okay. Okay.

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

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

material is.

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

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

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

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

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

It seemed to be absolute terms - all

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

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

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

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

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

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

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

OPERATOR: If no further comment from Mr. Leahy?

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

OPERATOR: I have Bob Link from Areva.

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

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

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

OPERATOR: Last question or comment -

Sidney Bernsen, independent consultant. Your line is open.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Hearing none, are there any questions on the phone?

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

Your line is open.

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

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

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

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

Section 21.71. Does that answer your question?

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

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

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

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

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

MR. MCCARTNEY: Yes, I agree.

MR. PRESCOTT: Okay.

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

MR. PRESCOTT: Thank you, yes.

MS. HUCKABAY: Yes, thank you.

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

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

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

it for the last 20 years.

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

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

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

MR. PRESCOTT: Okay. Thank you.

OPERATOR: No further questions or comments in the queue.

MS. HUCKABAY: Okay. Thank you.

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

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

(1:01 p.m.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

fact corrected.

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

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

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

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

OPERATOR: No questions on the phone.

MS. HUCKABAY: Okay.

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

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

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

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

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

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

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

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

MR. HEATH: The schedule we provided was

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

MR. NICHOL: Okay.

MR. HEATH: I'm sorry.

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

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

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

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

MR. PRESCOTT: Thank you.

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

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

MR. HEATH: Thank you, George.

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

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

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

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

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

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

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

MR. HEATH: Right.

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

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

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

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

Does that make sense? Does that comment make sense?

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

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

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

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

MR. HEATH: Right.

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

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

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

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

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

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

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

But by the same token we want to make sure

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

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

MR. HEATH: Right.

MR. DUNKELBERGER: So sounds good. Thank you.

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

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

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

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

MR. DUNKELBERGER: Agreed. Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Just wanted to wrap it up here by saying,

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

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

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

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

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

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

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

MR. PRESCOTT: Thank you.

MR. LOOMIS: Thank you.

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

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

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

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

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

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

an evaluation, now then the supplier must inform.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

forth.

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

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

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

MR. MARSHALL: Yes.

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

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

understood.

So that works for me on that. Thank you.

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

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

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

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

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

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

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

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

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

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

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

originally relatively simple. End.

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

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

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

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

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

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

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

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

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

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

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

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

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

Some people will probably need a --

MS. ATACK: Okay.

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

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

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

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

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

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

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

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

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

On Slide 97, you'll see the existing

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

These just are -- the purpose of these

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

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

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

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

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

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

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

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

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

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

So the left hand column identifies a

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

that's it. Thank you.

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

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

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

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

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

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

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

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

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

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

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

However, we did feel that there's value in

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

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

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

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

You know, some might identify the IROFS

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

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

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

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

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

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

(No response.)

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

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

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

OPERATOR: All right. One moment please.

(Off-microphone comment.)

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

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

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

OPERATOR: Understood.

(Off-microphone comment.)

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

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

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

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

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

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

MR. ROGERS: Yes sir.

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

MS. ATACK: Go ahead, William.

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

(Laughter.)

OPERATOR: Thank you however, Mr. Rogers.

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

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

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

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

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

essentially three.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

the rule for consistent implementation.

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

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

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

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

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

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

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

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

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

to Part 20.

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

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

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

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

events.

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

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

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

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

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

(Pause.)

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

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

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

MR. WARE: Sabrina, William Ware with the Southern Nuclear Operating Company. First, a disclaimer. I'm not that familiar with the stipulations to the Part 70 licenses. But in the discussion, you had mentioned risk-informed, and Marc Nichol had pointed out that for the power reactors, typically we've used a deterministic classification, and I was just going to suggest that for consistency, power reactors have the option of using the risk-informed, and like for Plant Vogtle, we just got

a license amendment to apply the 50.69, and we're not sure, you know, in the power reactor world, if that's going to prove to be a viable option or not.

But just, you know, big picture for the future. Under the risk-informed provisions of 50.69, for safety-related low risk components, Part 21 does not apply.

So you know, for consistency across the regulations, if you're looking at risk-informed, you might consider those provisions in 10 C.F.R. 50.69, and how those risk categories would correspond to risk categories for other categories or other types of licenses, so that those requirements would be consistent across facilities using the risk-informed methodology.

MS. ATACK: Yeah, we did take a look at that, and it was difficult to translate 50.69 into the regulatory infrastructure under Part 70. So yeah, it's a valuable piece of input, and yeah, I appreciate that. Thank you.

MR. WARE: But like you mentioned, there is the pitfall of when you make changes in the facility, you can change your risk categorization, and move in and out of categories, which would move you in and out of

reportability space. So there are some complications there. But I was just suggesting that historically, power reactors have not used the risk-informed. We're doing some pilots. We don't know where that might go.

So you know, just for long-term applicability of the regulations, you might want to look at that, just to make sure we're consistent from a risk-informed standpoint on the different applications. Thank you.

MS. ATACK: Great, thank you. Any other comments in the room?

(No response.)

MS. ATACK: Are we completed with the questions on the phone for this topic?

OPERATOR: We actually have three commenters on the phone.

MS. ATACK: Okay, we're ready.

OPERATOR: Nancy Parr from Westinghouse, your line is open.

MS. PARR: Hi Sabrina.

MS. ATACK: Hi Nancy.

MS. PARR: The first comment is basically a philosophical one, and there was a gentleman in the audience who was talking about his participation in the

original Part 21 rulemaking, and he expressed some concerns that these proposed revisions are not really in line with the original purpose of the rule. I really look forward to reading his comment letter. So please do submit that.

While I didn't participate in the original rulemaking, his comments are consistent with how my predecessors trained me, and as I understand it, and this is in layman's terms, one of the original purposes of Part 21 was to quickly inform companies who used similar safety components, that they procured of a defect in a component, that could cause problems, substantial safety hazards at their sites.

With all of the reactor community using many similar safety components, and also having Appendix B type programs, it pretty much was an operating experience program, where if you bought a safety component and there was a defect in it, it was made wrong in some form or fashion, then you want to get that word out quickly to the community who uses that component, because they could have similar problems at their facility.

And in the context of the fuel cycle facility, and in the context of IROFS, I think we lose

a lot of that original purpose of Part 21. Most of the fuel cycle facilities do not have Appendix B programs, our processes and hazards are very different, and so are our IROFS. So we're not really procuring basic component, and you know, this issue of having a defect in a component that we all use is not very likely.

And I believe that someone mentioned earlier, we have looked at the notification reports that the fuel cycle facilities have reported over the years, and we have not found any that would have tied to a substantial safety hazard.

The second aspect of my philosophical issue is getting to the definition of a basic component for a fuel cycle facility, rather than focusing on the definition of substantial safety hazard. I would have like to have seen us work first on the definition of substantial safety hazard, and then from that, determine which components meet the criteria for a basic component.

It kind of seems to me like it's that in this proposed basis, in the reverse order, it's like we said okay, this is want it to be, basic components. Let's figure out how we tie that to 10 CFR Part 70 and the performance requirements.

So in what I think that causes, the problem that creates, is that it appears to me that fuel cycle facilities have a lower consequence threshold for basic components than the reactors do. So that, that kind of summarizes my philosophical points. I do also have a very specific question on Slide No. 101.

When we are talking -- it's Slide 101, and we're looking at the independent criteria for IROFS, I'm wondering what the definition of independence is, and the example I would give if IROFS A were controlling level, and it was using one technology such as like a differential pressure bubbler, and IROFS B also is measuring level control, but it's using some, you know, source or radiometric technology, are those two different IROFS considered independent?

MS. ATACK: Yeah, Nancy. For the description you provided as an example, I would consider those to be independent IROFS, because they're using different technology to perform the needed safety function of monitoring the level.

MS. PARR: Okay, good, and that's all I had to say.

MS. ATACK: Other comments Nancy?

OPERATOR: Two more commenters from the

phones. If possible, our next commenter is Scott Murray of Global Nuclear Fuels.

MR. MURRAY: Hi Sabrina, it's Scott Murray. I noticed there was a subtle but very significant shift going from Slides 100 and 101, and then when I get to Slide 102, there in the upper right hand it talks about a defect or a failure to comply could cause the performance requirements of 70.61 to be exceeded.

Previously, you were talking about preventing and mitigating an accident. Was that an intentional redefinition, or are we using the term "performance requirements" consistently?

MS. ATACK: Yeah, I think that was unintentional. It was just two different ways of looking at the way to assess if something is a basic component or not. I think in the previous slides, the idea was that you would have assessed the IROFS needed in order to comply with the performance requirements as a result of the ISA process in which you analyzed accident sequences.

MR. MURRAY: Well let -- let me try to help then, because I'm very confused or I'm concerned that we're looking at the consequences, you know, the things

that happen in 70.61 that define a high consequence event, such as the dose and other things that you've been talking about. But in reality, 70.61 describes the risk of these credible high consequence events must be limited due to use of controls, to make them highly unlikely.

And I think as you understand, the term "highly unlikely" for most of the existing facilities was defined and accepted by NRC as basically less than or equal to 10 to the minus 4 events per year. And the loss of one more IROFS simply means you no longer meet that performance requirement.

In other words, the arithmetic risk now changes from 10 to the minus 4 to something like 10 to the minus 3, or 10 to the minus 2. It concerns me, because if you look at Appendix A, that simply means that's an event report, but it does not necessarily mean that you've now created a substantial hazard.

In other words, on Slide 102 I would have thought it would have been much clearer, and maybe throughout the rulemaking, if what you meant was the effect or failure to comply could cause a high or intermediate consequence event, because that's I think what you've been talking about, not merely the fact that

the performance requirements are exceeded.

MS. ATACK: I think that I -- one second, let me make some notes, Scott.

MR. MURRAY: And I'm concerned, because the term "performance requirement exceedance" is very different than for a fuel cycle facility under Subpart H, than for example on the reactor side, where they're worried about true risk, for example, loss of a containment boundary or core damage or some shutdown margin.

Our performance requirement exceedance simply means we've gone from that arithmetic risk of highly unlikely to something more than that, 10 minus 4 to 10 minus 3.

MS. ATACK: Right, and I think the intent would be that the basic components are those IROFS that are needed to ensure compliance with the performance requirement, and it's not that the only items that would be basic components are the one where if it fails, you're going to have a significant event.

MR. MURRAY: Well then we need to have a lot more debate about this during the rulemaking, because that is a significant change and I think, as several people pointed out, a significant difference in the

way we've applied our ISA. We use a number of IROFS, both administrative and engineered, to meet performance requirements.

And the loss of any one of those simply means you no longer meet that arithmetic risk. You do not in fact, as a result, create a substantial hazard.

MS. ATACK: Right. I think that's consistent --

MR. MURRAY: So if that's really what you meant throughout this, and that's what you've used further throughout, on Slide 102 and on, then like I said, I think we need to continue to pay very close attention to this, because that's not the way we've applied our ISA or I think intended to apply Part 21 to it in the past.

MS. ATACK: Yeah, and I think that the intent of Part 21 is not that basic components are only items where you would have a failure and immediately have some consequence to the worker or the public. I think both within reactors and fuel cycle facilities and other facilities regulated under Part 21, basic components are part of the overall safety equation at a facility.

I don't think that a basic component should

be something that's just the last layer of protection from, you know, a chemical release or, you know, criticality accident. I don't think that's an appropriate way to identify basic components.

MR. MURRAY: Well I think again, we may be talking past each other still Sabrina, because the term "performance requirement" is not the event. The term performance requirement in 70.61, I believe, is a simple arithmetic risk factor, to cause something to become highly unlikely. For most existing facilities, it's 10 minus 4.

And I don't understand how the exceeding that performance requirements, 10 minus 3 by itself is a substantial safety hazard. You're still 1 in 1,000 a risk factor. We'll have to flush this out through rulemaking apparently. That's all.

MS. ATACK: Okay. Thanks Scott. I mean yeah, there may be some lack of clarity in the wording I've used on the slides. But I guess my train of thought was such that in the Integrated Safety Analysis process, you evaluate all credible accident sequences, and then identify the IROFS that are needed in order to prevent or mitigate the consequences of those accident sequences, in order to comply with the performance

requirements.

And that correlates to the discussion we had a little bit earlier, where we're really looking at those basic -- those IROFS that are necessary in order to ensure compliance with the performance requirements, to determine which ones will be a basic component.

So like you said, there are a lot of IROFS that are in place, and the consequence of one failing may simply be that you're less protected from a consequence than actually having the consequence. But that is part of the proposed definition that the staff has provided. It's not that a basic component will be an IROFS whose failure would result in a direct accident and would definitely result in a specific hazard.

It's something that the licensee has determined is necessary in order to ensure safety at the facility, such that the performance requirements could be met. Those items would be basic components. But again, it's only those that are necessary in order to ensure compliance with the performance requirements.

So if you have multiple IROFS, and again taking into account the engineered administrative portions of the proposed language, if you have multiple IROFS, engineered IROFS for instance that are diverse

in nature, then none of those would necessarily need to be basic components, consistent with what's provided on the slides, if those are independently capable of preventing or mitigating the accident that you analyzed in the ISA and determined that you needed those IROFS in order to meet the performance requirements, to limit the risk.

OPERATOR: We have one comment from Charles Slama of Urenco. Your line is open.

MR. SLAMA: Hey Sabrina.

MS. ATACK: Hi Chuck.

MR. SLAMA: I guess real quick, going back on this discussion that's been ongoing, it seems to me that we did not -- well, this is kind of hard for me to explain, I guess, without my ISA folks here. But we do our ISA analysis to determine whether we need an IROFS, to not only reduce the likelihood, but also mitigate the consequences should an accident occur.

So if I -- the way that we've always approached this is if I have a component out there, and I find out that there's something, that there's a defect that exists due to manufacturer error, specifically with their implementation of their QA program, and I find out that that defect, should that postulated

accident sequence occur, that the IROFS would not perform its safety function, I would exceed either intermediate or high consequence, either the likelihood or the consequences, then that's definitely something I need to report out in Part 21.

I don't know. It's just I'm kind of lost in the misunderstanding that exists, maybe from some of the other facilities. But what I want -- the other thing I wanted to talk about, on your tables on Slides 100 and 101, it seems to me that a lot of these IROFS, if you're saying that you have an administrative IROFS and an engineered IROFS capable of independently preventing or mitigating an accident sequence, then why would you have --

If something is not going to be a basic component, then that tells me that it probably doesn't need to be an IROFS, because it's not necessary to meet the performance requirements of 70.61. I think maybe they're -- maybe it's just there's an extra layer of IROFS on here that don't need to be here, and maybe in some cases it's just defense in depth and doesn't necessarily need to be defined as an IROFS.

In the case of two IROFS that are required due to their failure probabilities, yes, I can see where

two IROFS would be required to meet the performance requirements, that is the likelihood and consequence mitigation. But if they are independent IROFS and only one of them is needed, maybe there's some confusion in adding that whole extra level of IROFS for defense in depth, that's not required to meet performance requirements.

MS. ATACK: Thanks Chuck, and I think what I've heard in some situations is that there are different philosophies in determining which items should be designated -- items and controls should be designated -- as IROFS.

Some facilities will err on the conservative side, such that if they have an IROFS that is found to be unavailable, there are additional IROFS that are designated in that sequence, such that they wouldn't have to make a report under Part 70.

MR. SLAMA: Okay. Well I guess my argument would be then if there's a failure probability they're concerned about, then both of those IROFS would have to be basic components, because if one of them failed within some frequency that wasn't acceptable to meet performance requirements, then you're depending on that other one to account for that failure probability.

MS. ATACK: Thank you. Do we have other comments or questions from the phone?

OPERATOR: No further comments or questions from the phone.

MS. ATACK: Hey, we made it through the basic component discussion. I think we all knew that was going to be the worst of the -- well hopefully that will be the worse of the -- sections that we'll be discussing for fuel cycle facilities.

So I do appreciate the active discussion and the comments, and we'll definitely consider them moving forward, as we finalize the regulatory basis, and then enter into the proposed rule phase and start drafting guidance, which will be a large part of the equation for fuel cycle facilities.

Next we'll discuss Section 15 of the draft regulatory basis for evaluating reporting, and the subject is lack of clarity in the evaluating and reporting requirements for Part 70 licensees.

As you can see, 10 C.F.R. 21.21 describes the evaluating and reporting requirements for entities that are subject to Part 21, and the requirements do state that entities to which Part 21 applies must develop procedures to evaluate deviations and failures

to comply, to identify defects and failures to comply that could create a substantial safety hazard if they were to remain uncorrected.

Moving on to Slide 105, you'll see the existing regulatory framework. This regulatory framework slide talks about the promulgation of Subpart H to 10 C.F.R. Part 70, which most of you who have had a participating role in this discussion are very familiar with.

In 2000, the NRC amended Part 70 to incorporate new requirements for the development of an Integrated Safety Analysis for fuel cycle facilities that are authorized to possess greater than a critical mass of special nuclear material.

In the development of Subpart H, the Commission did seek to apply risk-informed and performance-based approach, that included the identification of performance requirements for the prevention of accidents, or the mitigation of their consequences, as well as the performance of an Integrated Safety Analysis to identify potential accident sequences at the facility and the items relied on for safety needed in order to maintain the risk to an acceptable level.

The implementation of a system of management measures was also part of the promulgation of Subpart H to 10 CFR Part 70, and the goal of the management measures program is to ensure that items relied on for safety are available and reliable to perform their safety function when needed.

As we've discussed in the past hour, the existing regulatory infrastructure under Part 70 does provide a high level of flexibility to licensees in the conduct of their Integrated Safety Analysis, as well as the determination of what controls need to be items relied on for safety.

The regulatory issue we have in the evaluating and reporting regime for fuel cycle facilities is that there's a lack of clarity as to whether the implementation of Part 21.21 does enable consideration of the risk-informed and performance-based approaches, like those implemented in 10 CFR Part 70.

To date, there's been limited guidance available for evaluating and reporting for fuel cycle facilities, so it has been difficult for stakeholders to understand how to perform evaluations under the existing regulatory framework.

The staff does believe that consideration should be given to aligning Part 70 and Part 21, in order to ensure regulatory clarity and stability. As such, the staff is proposing to prepare guidance related to Part 70 evaluating and reporting. The guidance will delineate when licensees should conduct an evaluation, and how that evaluation can be performed in a manner that allows credit for the risk-informed performance-based approaches defined in the Part 70 regulatory infrastructure.

A diagram -- excuse me. A diagram is provided on the next slide to provide further clarification of the proposed process. We are now on Slide 109, and in this diagram you'll see a flow process, in which you start with a deviation in an IROFS that has been identified as a basic component.

So you can take two flow paths. The first will be during the evaluation, you determine that administrative IROFS are available, that would have prevented the performance requirements from being exceeded. In that case, that is the deviation is not a defect, no report to the NRC is required under Part 21, and the only thing that the licensee needs to do in order to comply with Part 21 is to retain the documented

evaluation that was performed.

On the right-hand side of the flow process, you would see an evaluation in which an administrative IROFS was either not designated or was not available to prevent the performance requirements from being exceeded. In that scenario, you would have a defect that's reportable under Part 21, and consistent with Part 21 requirements, you would also retain the documented evaluation.

Now it is time for questions on the proposed guidance for evaluating and reporting for fuel cycle facilities. Do we have any questions in the room?

MR. SCHILTHELM: So this is Steve Schilthelm with B&W. If you go back to your last slide, 109, and then you think about the purpose of Part 21, Part 21, at least what we've heard throughout the day, was to get information out to other users, other licensees, about things that could impact them at their site.

If you look at this slide, it kind of illustrates the point that it appears as though for fuel facilities, you're trying to implement an ancillary event reporting system, because this is very site-specific. It wouldn't necessarily inform other

licensees, who may be using a component differently. It's just a very site-specific criteria that says I do or don't have to report under Part 21.

But that doesn't seem to align with the real intent of Part 21, which is to get information out to other licensees and other users. So it seems to be a disconnect.

MS. ATACK: Yeah, and I think the flow chart doesn't speak to those elements of Part 21. I think there are two aspects in which that function would be performed after a report is made. The first would be similar to what Nancy Parr mentioned, you know, in terms of an operating experience program. Our licensees are continuously monitoring Part 21 reports and other reportable events, to determine if there's anything applicable to their facilities, and I know the fuel cycle industry does participate in, you know, biweekly calls.

So there's some degree of communication that occurs, such that the industry can share information to determine if there's an issue that might be relevant across the board to more than one facility. The other part is what happens at the NRC, when we receive a Part 21 report, and we will assess that Part

21 notification, gathering the additional information we need with the licensee or the vendor, and then determine if any further regulatory action is needed.

That could take place in the form of an inspection, that could be a generic communication, you know. It could be an information notice that says okay licensees, we've had failures in this type of a component. This was of safety significance. You should evaluate if there's any significant -- excuse me, any similar item in use at your facility, and if there is, consider taking appropriate actions that will be relevant to the safety performance for your facility.

That's how the Part 21 reports are used in order to improve safety, though you know, it's the expectation that licensees would be aware of those Part 21 notifications, and are actively looking at them. But it also takes place here at the NRC, and it's also our role to evaluate them and determine if need to do any further outreach to the industry.

MR. SCHILTHELM: But in this particular slide, as you go down the left-hand chain, depending on site-specific use of a component, NRC would not be notified. So that you're getting into a very site-specific use space, versus generic implication

space I guess is the point I'm trying to make.

MS. ATACK: That's true, and yeah. And it's difficult to find the perfect equation that would allow us to receive notification of failures that may affect other licensees who are using things differently. So I do acknowledge that there are potential missed opportunities for information to be shared as a result of this infrastructure.

But again, the staff would be able to look at those evaluations during the inspection process, when inspectors are on site, and at that time the inspectors could have the potential to identify something that may be applicable to multiple licensees, and could take that back for further action, to communicate it.

MR. NICHOL: Marc Nichol, NEI. Just a procedural question. So in this and a couple of other -- of your other issues, you identified proposed guidance. So could you elaborate on what the NRC's plans are and status for developing the guidance? Is it going to be one guidance document, multiple documents?

MS. ATACK: The plan is that it would be -- the two draft guides that have been identified, 1291 and

1292 for accompanying the proposed rule would contain all of the relevance guidance for Part 21 evaluation, excuse me, evaluation and reporting and commercial grade dedication respectively.

So the goal would be that the staff would provide, you know, potential endorsement of industry documents, as well as specific implementation guidance, like what we're discussing during this presentation, as part of those reg guides.

Do we have any question -- oh, one other question in the room.

MR. WEAVER: Hi, Doug Weaver, Westinghouse, and maybe this is a simple question. But can you give an example.

When would you have something that's reportable under this guidance that you've outlined in this slide, and not be reportable under, I guess it's 70.74? You know, if you have an IROF that's degraded, so that you can't meet your -- isn't that already reportable I guess is my question, and what additional types of things are you capturing here? Thanks.

MS. ATACK: I think what Part 21 really captures that's not in the existing reporting requirements under Part 70, and I think this statement

is true for many of the reactor scenarios and someone can correct me if I'm wrong. But it's really before you have a failure, you know. It would be something that, you know, it's a deviation.

So it's much further upstream than what you would find in many of the other reporting requirements. So it's something that has the potential to cause an issue if it remains uncorrected. So it could be something as simple as "we procured a tank and we thought it was a certain material, but it turns out that it wasn't."

Or "we installed something and we thought the welds were great, but they're not." Or "we just, you know, we determined during maintenance that we have a lot of issues with the welds that were credited with part of performing the IROFS function for this system." So those are the -- to me -- the most significant things we would catch as part of Part 21, that you wouldn't catch further downstream in the reporting requirements.

Do we have any questions on the phone?

OPERATOR: We do. Bob Link from AREVA, your line is open.

MR. LINK: Thank you. Slide 109, again if I'm interpreting it correctly, appears to be

inconsistent with what you presented in the previous section of the discussion.

That is, in the evaluation boxes, do you really mean just administrative IROFS, though other IROFS are evaluated within the context of the evaluation for Part 21? I would have expected you to say administrative IROFS and/or independent diverse engineered IROFS are not designated or available to prevent a performance requirement.

You're exclusively saying administrative IROFS, which is --

MS. ATACK: Yeah. We're showing how administrative IROFS are credited in the evaluation process, because they're not credited in terms of identifying what should be a basic component.

So, and I'd have to go back and really take a sharp look at this. But I think the intent was that if something is a basic component, if an engineered IROFS does meet the criteria to be a basic component, then you wouldn't be in the evaluation process able to find another engineered IROFS that would perform that safety function, because if that were the case, it wouldn't be a basic component in the first place.

MR. LINK: Well now I am confused, but with

regard to the earlier examples, but I think we can discuss that further.

The other aspect in terms of reporting, actually you're kind of alluded to in this section, and that is the question I had earlier today, relative to whether or not, you know, 70.50, Appendix A reporting and even 71.95 would if the licensee explicitly included that it's reporting at Part 21, and provided all that information as necessary by the rule, I would expect that those would satisfy the Part 21 reporting requirements.

MS. ATACK: That's true. Thanks for looping back on that Bob. I did have a note to follow up on it. So there's, like we said earlier, there's no specific provision for Part 70 licensees specifically. But if you look under 21.21(d) in the existing rule, it's -- I'll read it for you if you give me one second.

(Pause.)

MS. ATACK: So in short, I'm sorry. Let me find it.

(Pause.)

MS. ATACK: It's 21.21(d)(2), states that "The notification to the NRC of a failure to comply, or of a defect under paragraph (d)(1) of this section, and

the evaluation of a failure to comply or a defect under paragraphs (a)(1) and (a)(2) of this section, are not required if the director or responsible officer has actual knowledge that the Commission has been notified in writing of the defect or failure to comply."

So that's the citation that provides credit for reports that have already been made, and again I'd like to loop back to the importance of identifying that the report that's being made is also a Part 21 report.

So if you do make a report under another reporting requirement, in order to notify the staff that that does also serve the function as the Part 21 report, we would expect that you provide all the necessary information consistent with the Part 21 reporting requirements, and also identify that it's a Part 21 report.

MR. LINK: Okay. I think you said yes.

MS. ATACK: Yes, I did say yes.

MR. LINK: And I don't want to belabor it, but I'm still trying to make sure that I understood maybe your scenario back on Slide, I'm going back now, 101 far right, where you had no IROFS for basic components. So if I have a failure of A or C or B or C I should say in that scenario, back to your Slide 109, that is or is not

reportable?

MS. ATACK: Let me see if I understand your question Bob. You're saying on Slide 101, the far right column, if you have a failure of IROFS B or C, you're asking if that would be reportable?

MR. LINK: Correct.

MS. ATACK: No, because neither B nor C are basic components, because in the absence of B, C would be available to perform the safety function. In the absence of C --

MR. LINK: Because that gets back to my concern that I stated before, with on 109 just stating administrative IROFS, rather than administrative and/or engineered IROFS that are basic components I guess is the issue. Anyway, it's going to be a challenge for both of us to write good guidance to be able to implement that in a consistent way.

MS. ATACK: True, and I will think about that one. Obviously, we have a lot of time that we will be spending in terms of preparing the guidance. I understand your point. What I'll have to think about is if there are any situations in which you would have a basic component when you -- in your evaluation, you would consider the availability of other IROFS that are

engineered.

Because like I said, I think in these slides, you know, 101 and 100, which precedes it, you actually go through the process of evaluating how many engineered controls you have available that are capable of performing the safety function that's credited in the ISA.

So that part actually accounts for the additional engineered IROFS that are available, such that you wouldn't need them in the evaluation process, but I could be wrong on that. So I'll definitely take a closer look at it, and I'm sure we'll have more discussion as we talk about preparing guidance.

MR. LINK: And just to be clear, I guess my -- you know, one of the significant administrative burdens that this definition, I'm going back to the definition again I acknowledge, would indicate, would mean that every licensee under Subpart H would have to go back and essentially rescreen each and every IROF and each and every scenario, to create an understanding of what IROFS are basic components and which are not.

That is a -- and then obviously it's a living process, so as we change, either adding IROFS or changing out IROFS or deleting IROFS, that would change

what becomes a basic component under this proposal.

MS. ATACK: That is true. Thank you, Bob. Yeah, part of the flexibility that's inherent to the ISA process and the change processes that are available for performing and updating the ISA, would provide such that -- the situation such that -- you would have the potential for having a change to what items are considered basic components over time, as was previously mentioned in the comments.

So yeah. That's something we'll have to look at as we move forward. Any other questions on the phone or comments?

MR. LINK: We'll just add it to the cost of implementation.

OPERATOR: Scott Murray of Global Nuclear Fuels, your line is open.

MR. MURRAY: Yeah, I appreciate that. Bob actually took some of my question that I said I was confused by the idea of administrative IROFS in the scheme of things.

I will point out that this also tends to set up a separate additional reporting criteria, not related to performance requirements, because there are certain criteria that make something not reportable.

ISG-12, for example, that allows crediting other controls, and they're not administrative. So Sabrina, this needs a lot of help, I think.

The one other comment I can make, we rarely use purely administrative controls to meet performance requirements. We can. Administrative controls usually only have a 1 in 10 reliability factor. So you theoretically for our -- to make something highly unlikely, we need four of them. But the unintended consequence here is that we could theoretically add additional administrative controls, and still meet performance requirements.

So even if that original engineered IROFS was a basic component, this would seem to imply that I could have multiple administrative IROFS in addition to that one, and it would not be a defect. So that this slide is very awkward to understand, and as Bob pointed out, we would have to go back and reanalyze many of our IROFS and accident sequences, to even see how this could apply. A lot of work on this one.

MS. ATACK: Thank you, Scott. Yeah, I think there would be differing levels of work, depending on how the licensee has conducted the ISA and the outcome, in terms of how many IROFS were identified,

such that if the licensee only identified the IROFS that are necessary for compliance with the performance requirements, that evaluation of what would be a basic component would be a bit more simple than the licensee who may have gone and credited several IROFS to provide defense in depth, even though not all of those are needed in order to meet the performance requirements.

So yes, there's some potential that additional evaluation would be needed, in order to determine what would be a basic component. I am aware of NRC guidance that allows crediting items that are not identified as IROFS, and I think that would be something that we would address, as part of the guidance development.

MR. MURRAY: Thank you.

MS. ATACK: Any other comments or questions on the phone?

OPERATOR: Charles Slama of Urenco, your line is open. Mr. Slama, your phone might be muted.

MR. SLAMA: You're right. Hey Sabrina, now that we've had some further discussion, I think I can clarify what I was trying to say during my last comment.

When I read these scenarios, specifically

situations where we have two independent engineered IROFS that can independently meet the safety function, you've said that neither of those would be a basic component, because any of those independently will meet the performance requirements.

But it's my understanding that most times where you have two engineered IROFS like that, they're independent for common cause failures, and that's because of their failure probabilities. So you do need both of them in actuality, to meet the probability numbers, as defined in the high and -- or intermediate and high consequence events.

Could you provide some clarification on that? Is this meant to truly mean two IROFS that can independently meet all of the -- so for example, on this third column on the -- we'll go back to Slide 101, you're saying if I got rid of IROFS C, IROFS B all on its own can meet the consequence mitigation and likelihood reduction all on its own?

Or is it okay if we are truly in our ISA analysis counting on both of those for likelihood reduction? However, if one fails, we're not going to call it a basic -- we're not going to have a Part 21 report, because they're both there?

MS. ATACK: Let me try to provide an answer, and then maybe you can tell me if I understood your question. We'll do this in an odd manner. If I understand your question correctly, you're asking if in the event that both IROFS were needed in order to meet the performance requirements, and one failed or one had a deviation, what would be the outcome of the evaluation, in terms of -- let me just try this, okay.

If you have two IROFS that are credited with -- in order to meet the performance requirements. So they both provide some sort of a risk reduction. The only ones that would need to be basic components would be those in which you need it in order to meet the performance requirements. So if one of those is independently capable of meeting the performance requirements and you have two of those, neither would be basic components.

MR. SLAMA: Okay. I think maybe that's where my confusion came in, because all right. So in this scenario that we have here, in this third column on page 101, in reality what we're saying is one of these is just a defense in depth. I could really have met my performance requirements and operated my plant with IROFS A and B; C doesn't even need to be there?

MS. ATACK: That's true, that's true. In the far right column, you wouldn't need all of them in order to comply with the performance requirements. So one would be designated as an IROFS, and that would -- that would be a defense in depth measure, because if IROFS B failed, you would still have C, which is capable of ensuring that you comply with the performance requirements. Or if IROFS C failed --

MR. SLAMA: IROFS C truly could just be piece of equipment X. It doesn't even have to be called IROF C. It doesn't have to be an IROFS. It's not an item relied on safety per se, because it's not required to meet the performance requirements.

MS. ATACK: That would be true.

MR. MURRAY: Okay. That's where my confusion was. I was trying to understand.

MS. ATACK: Yeah. I understand what you're saying, and yeah, and I think I was trying to address that in the comments section of those boxes, where it talks about if it's capable of independently performing that safety function. So you know, consistent with Scott's comments, I probably should be very cautious of the terms I use in the slides, because that, you know, they're subject to interpretation.

MR. SLAMA: Okay.

MS. ATACK: Yes. I can address that.

MR. SLAMA: Okay, thanks.

OPERATOR: No further comments in the queue.

MR. MURRAY: Okay. That brings us to a break. So shall we take ten minutes? Back at 3:35? 3:35.

(Whereupon, the above-entitled matter went off the record at 3:23 p.m. and resumed at 3:37 p.m.)

MS. ATACK: Our numbers are dwindling, but hopefully everyone's energy level is high. I think that the commercial grade dedication section will be a little bit less controversial than the evaluation and reporting portion, or at least I hope so.

So, hopefully we will move more quickly through this section than we did the previous portion of the presentation. We'll start with Section A of the draft regulatory basis, which covers a lack of regulatory guidance for commercial grade dedication as it applies to fuel cycle facilities.

I'm on Slide 113 now, where we describe the existing regulatory framework. The current definition

of dedication for nonreactor facilities simply states that dedication occurs after receipt when that item is designated for use as a basic component.

The NRC has issued a limited amount of guidance on commercial grade dedication, but the guidance that has been issued has been more focused on reactors, which has left a void in the regulatory framework for dedication as it applies to fuel cycle facilities.

So, the problem as it stands now is that there's currently no NRC-issued consolidated guidance for an acceptable form of dedicating commercial grade items for fuel cycle facilities.

As a result, stakeholders don't have the guidance they need to convey NRC expectations for the conduct of dedication activities, or to help ensure the dedication is performed properly.

When the staff added Subpart H to Part 70 in 2000, it included requirements for licensees to implement a system of management measures in the revised rule, which we discussed previously.

For plutonium processing and fuel fabrication facilities, those licensees were also required to comply with Appendix B to 10 CFR Part 50.

At the time Subpart H was promulgated, the staff didn't evaluate the implications of these new requirements to determine if any conforming changes to Part 21 were needed.

Further, the guidance that is currently available for dedication is geared towards facilities that comply with Appendix B to 10 CFR Part 50. So, there's a need to provide guidance that is directly applicable and relevant to fuel facilities and that aligns with our regulatory infrastructure.

On Slide 115, I describe the proposed guidance as being set forth in the regulatory basis. In order to resolve this regulatory problem, the NRC is proposing the development of guidance that will clarify that licensees that are subject to Subpart H of 10 CFR Part 70 and are not subject to Appendix B of 10 CFR Part 50 may satisfy the requirements of commercial grade dedication by implementing their existing management measures programs under 10 CFR Part 70.

It is the staff's position that the implementation of these management measures programs ensures the availability and reliability of IROFS at fuel cycle facilities for the purposes of design, procurement, installation and maintenance.

Then NRC reviews and approves licensee management measures programs as part of the safety program required under 70.62, and we ensure the effective implementation of those measures through routine inspections.

For fuel cycle facilities regulated under Subpart H, and subject to the requirements of Appendix B to 10 CFR Part 50, those would be the plutonium processing facilities, the proposed rule changes described in the regulatory basis will clarify the applicability of Appendix B QA controls to the dedication process, and we'll discuss those changes in subsequent slides.

Section B would be those subsequent slides. So, before we move onto that, does anyone have questions on Section A? Anyone in the room? Anyone on the phone?

OPERATOR: Star 1, and record your name and affiliation.

MS. ATACK: Hearing none, I'll move onto Section B, since Sections A and B do have a high degree of interrelations. So, if you didn't have an opportunity to ask a question on Section A, you might think of something as we go through Section B.

Section B covers the proper place for

dedication requirements. The existing regulatory framework, as we previously noted, lies in the definition of dedication in the current rule, and that -- excuse me, that definition is very simplistic. Again, it just states the dedication occurs after receipt when that item is designated for use as a basic component.

I'm sure you can acknowledge that there would be a large degree of variation in how licensees may interpret those words.

On Slide 118, we identify that the problem with the way the regulation is currently written is that not only is the definition lacking in detail as it applies to fuel cycle facilities, but it is generally poor practice for regulatory requirements to reside solely within the definitions. I think a lot of the discussion we've had within today's meeting identifies the need to promulgate separate requirements that will describe the expectations for commercial grade dedication, and Section B as it applies to fuel cycle facilities does acknowledge that as well.

So, going to Slide 119, we discussed the proposed changes to the regulations, and again this slide is two fold because part of the solution that we've

recommended is guidance for those facilities that are not subject to Appendix B, which we discussed in the previous section, and in this area we proposed changes to the regulations to acknowledge that those facilities that are subject to Appendix B as part of their licensing basis do have separate expectations than those who are not subject to Appendix B.

So, for the fuel cycle facilities that are subject to the requirement of Subpart H and Appendix B, the newly developed Section 2171 of the rule would apply.

Those facilities will also be expected to perform commercial grade dedication in accordance with their Appendix B QA programs.

As we stated previously, guidance discussed in Section A of the draft regulatory basis would be applied to communicate the link between management measures programs and performance of commercial grade dedication for those facilities that are not subject to Appendix B.

Do we have any questions on that section? Any questions on the phone?

OPERATOR: We have two. First, Nancy Parr from Westinghouse.

MS. PARR: Sabrina, one thing that concerns me about this is it seems like we're starting to mix and match management measures and the 18 criteria with Appendix B, and what we've found within our own company is that people generally understand Appendix B and then they frequently have a hard time understanding quality assurance being different in terms of management measures for Part 70 regulated facilities.

So, my concern is with mixing and matching of requirements can really cause a lot of future confusion when new people who haven't been involved in this come in with their own perspectives and interpretations.

So, it does confuse me, but why would a facility have to comply with management measures and Appendix B? Because in being involved in Part 70 Subpart H rulemaking, there was a lot of discussion that management measures was a lower tier, if you will, quality assurance program for fuel cycle facilities that didn't have the same risk as, say, a power reactor.

So, it seems redundant and confusing for a facility to have to comply with both. And some of the proposed rulemaking seems to stem towards addressing the problems caused by the facilities having a

management measures program and an Appendix B, and some of the exemption requests that they have issued.

So, again, maybe just another philosophical question but I don't understand what value you get from having a management measures program and an Appendix B program.

MS. ATACK: Thank you for the comment, Nancy, and I think the intent of the message I was trying to communicate is that for those licensees who have a commitment to comply with Appendix B either as part of their regulatory requirements under Part 70, which would be the plutonium processing facilities, which is limited to MOX, or those that have committed to comply with Appendix B, those would be the only facilities where we're providing the more prescriptive dedication requirements.

It is not intended to make the rule overly prescriptive or complex. The intent is to separate out those facilities that have more rigorous quality assurance requirement from those that have the expectation simply for a management measures program.

So, I don't think the staff has any expectation that licensees would have both a management measures program and an Appendix B program, and we would

use that as input into the way they do commercial grade dedication.

It is intended to be very simplistic, such that the rule directs facilities that have a licensing basis that directs them to comply with Appendix B to perform dedication in accordance with Appendix B, and they would also be subject to 21.71, whereas the facilities that don't have to comply with Appendix B would essentially complete commercial grade dedication as part of implementing their management measures programs.

So, that would essentially mean that you procure an item. You might do some sort of receiving process. But for fuel cycle facilities, there's a large degree of functional testing or post-installation testing involved as part of the receiving process.

So, my perception of how we would probably proceed with guidance is that an item would be a basic component after the completion of those post-installation tests when you've actually verified that it will perform its safety function. Does that help to answer your question or concern?

MS. PARR: It does, but this will probably come when we do the cost estimates as well. But using

the same terminology and saying commercial grade dedication for, say, an Appendix B Program and then having slightly different criteria for commercial grade dedication for a Part 70 facility without an Appendix B Program really adds complexity to your Level 2 QA procedures and those management systems and policies.

MS. ATACK: I think I'm failing to appreciate your concern, Nancy. Maybe I'm oversimplifying the situation. So, maybe you can help me understand it better.

The intent of what the staff is attempting to do through the rulemaking and the guidance would be to separate out the fuel cycle facilities such that those that comply with Appendix B as part of their licensing basis perform dedication the same way that reactor facilities do, and that's consistent with the way that the licensees are implementing it right now. And those facilities and activities that don't have Appendix B as part of their licensing basis would essentially continue to perform activities as they do now.

We would acknowledge that the performance of those management measures processes satisfy the intent of commercial grade dedication.

MS. PARR: And this difficulty comes from being a Part 70 facility without an Appendix B program on management measures activities are controlled, say, at a local level. And we do have a company-wide driven Part 21 program which we would use if we had to evaluate whether a substantial safety hazard could have occurred.

But when this company-wide Part 21 program is really the processes that evolve from it in the commercial grade dedication procedures are fairly complex for dealing with Appendix B and our product quality requirements. But they have typically left, say, the management measures aspects, they don't even deal with that. That's dealt through our license application and our local procedures at the license site.

I do believe that some of these proposed changes will further complicate our product quality processes and procedures.

MS. ATACK: Thank you for the comment, Nancy. Perhaps in future dialogues we can get into some more specific details so that I can understand your concern a little bit better and I can help inform our guidance as we get into that stage where we're working

to prepare guidance so I'm prepared to address your concern. Because right now, I don't feel like I have a firm grasp on the concern.

MS. PARR: That's great. We will take it offline, and talk in greater detail.

MS. ATACK: Thank you, Nancy.

OPERATOR: Next up is Bob Link of Areva.

MR. LINK: Thank you. This is more of a clarifying question. And I appreciate, Sabrina, your I guess willingness to acknowledge the management measures programs we have in place, and the -- while it's a difficulty in terms of what I would characterize as an Appendix B full blown dedication process.

But that being said, I want to make sure your words and your expectations match my interpretation of your words and that is if I apply, as I must apply via my licensing commitment, the management measures that are outlined in our license application, no further effort or activities would be necessary to dedicate a basic component other than what we discussed before in terms of the logic evaluation to identify those basic -- those items under your scenario in the IROFS scenario description.

We'd have to do that, but then as we acquire

items, catalog items or commercial items, whatever you want to call them, they, by the nature of our management measures process would then be anointed following our full receipt testing qualification requirements as represented.

In other words, and I -- I guess to be very frank about it, you would not expect to see a separate analysis per item that would identify all the critical characteristics and explicitly look at how we assure that those critical characteristics are fulfilled.

MS. ATACK: That is correct.

MR. LINK: Okay.

MS. ATACK: I think what we would seek to outline in guidance is the way that the management measures program satisfies the commercial grade dedication process and also I think one of the critical elements will be identifying when that item is designated for use as a basic component because of the large degree of functional testing and other processes that come into play before fuel cycle facility licensees are ready to declare that as a basic component.

I think that will be an area that we need to pay special attention to in order to make sure that we arrive at the right level of guidance that will

provide clear expectations for when an item becomes a basic component.

MR. LINK: Okay, thank you.

MS. ATACK: Your question made me think of another note I wanted to make, Bob. Thank you for that. This one applies to the Appendix B facilities, and I just want to note because we have approved some graded quality assurance programs.

So, for those Appendix B facilities that do have existing graded provisions provided as part of their licensing basis, those would continue to be valid. And in the event that any Part 21 rulemaking element would be more prescriptive than something that the staff had already approved as part of the licensing basis for a facility, then the licensee would continue to comply with those license basis commitments that the staff approved via safety evaluation report.

Do we have a question in the room?

MR. NICHOL: Mark Nichol, NEI. I apologize. Just for my own benefit to understand how these definitions and rules are applied to fuel cycle facilities: I'm trying to understand if a fuel cycle facility goes out to procure something, and let's just say this something could meet the definition of a basic

component, it -- or it could result in a substantial safety hazard if there were a defect.

So, if the fuel cycle facility is going out to procure this, is it always procured as commercial grade items that always are procured as a basic component? Could it be one or the other, depending on whether management measures were applied during the procurement process.

And I'm wondering because I don't really understand where that distinction lies. So, I'm wondering what the NRC's position is on that.

MS. ATACK: Well, I think it is more of a licensee position. I don't think we really determine how licensees procure things. What I've seen as part of our site visits and part of familiarity with some of our sites that are under construction and operating is it would be separate for the facilities to comply with Appendix B versus those that have management measures programs.

So, typically the Appendix B facilities would be procuring many items as basic components with qualified suppliers. The facilities that aren't required to comply with Appendix B would be doing much more of commercial grade dedication type approach by

implementing their management measures programs.

So, Bob Link may be able to speak to this because we visited his site, and he is very familiar with the ability of licensees to apply a graded process to their procurement as part of their management measures programs.

So, for instance, the Areva facility in Richmond. We saw a sliding scale depending on the safety significance and complexity of the items that are being procured. Whereas for the more safety-significant or complex items, it would be very close to an Appendix B type of procurement without necessarily invoking Appendix B in the procurement document. There may be some procurement requirements to invoke industry standards for more complex and safety significant items.

For other items such as plastic pails, which is a very common example we use for fuel cycle facilities, i.e. one that would hold UO2, those pails would be procured commercially and then it would be a simple kick and count and making sure that they don't exceed the volume that they are supposed to hold, and make sure that they're made out of the material that you would expect just by a visual type of examination.

So, for the non-Appendix B facilities, there's a sliding scale in terms of how they procure things, but I've seen very few things that I would deem as being procured as a basic component. I would say mostly all of them are procured as a commercial grade item, and the licensees' processes are what make it a basic component.

MR. SCHILTHELM: So, listening to that discussion and thinking back earlier to the discussion about changing the rule such that when you invoke Part 21 you also must invoke Appendix B. I think that was on one of the earlier rule changes. You might want to think about how that requirement would need to be tailored a little bit for a fuel facility who could invoke Part 21 but wouldn't necessarily be invoking Appendix B on the supplier. If I understood that previous discussion.

You could buy a -- you could invoke Part 21 on a supplier as a fuel cycle facility without invoking Appendix B. I believe.

MS. ATACK: You could. I don't know that we've seen that happen because what would need to happen in order for that to occur would be you would invoke Part 21 and a management measures program, which I've not

seen occur.

It is possible. I think if I recall correctly, maybe the discussion we had earlier was geared toward invoking Appendix B as part of procurements for basic components in which case I think we have addressed that in the guidance and the proposed rule changes such that the only fuel cycle facilities that would be required to comply with those Appendix B program elements would be those that are already subject to Appendix B.

Does that address your -- I understand what you're saying. I don't know if we said that earlier or not in terms of invoking Part 21 in the purchase order, but if we did we will make sure to take a close look at that because there is the potential that you would invoke Part 21 but not Appendix B. Probably a remote possibility, but it's possible.

Do we have other questions or comments on the phone?

OPERATOR: One from Scott Murray of Global Nuclear Fuel. Your line is open.

MR. MURRAY: Sabrina, I'm -- I want a clarification. I'm looking at slide 119, please. In the center section of that slide, it talks about

guidance discussed in Section A of the draft regulatory basis. I'm having a little difficulty finding specifically Section A. Can you help me find where that description is?

MS. ATACK: That would be the first subject under commercial grade dedication in the regulatory basis. Those were the slides that we discussed in the beginning of this segment of the presentation. Let me see if I can find the page.

MR. MURRAY: So, it is actually chapter 3?

MS. ATACK: Right, chapter 3.

MR. MURRAY: Okay, page 52?

MS. ATACK: Regulatory guidance on page 52.

MR. MURRAY: Yes, it wasn't obvious when you said Section A. I couldn't figure out specifically if you were talking about the commercial grade dedication chapter.

MS. ATACK: Right. In that, Section A does apply to all of the facilities that we're talking about as part of the rulemaking and guidance clarification. So, the lack of regulatory guidance is an issue for more than just -- more than just the fuel cycle facilities. So, that's probably why it is a

little bit harder to find that one.

MR. MURRAY: Yes, but specifically I think what I'm asking about is for that first bullet fuel cycle facilities subject to Subpart H but not subject to Appendix B, and I think the paragraph or paragraphs that you're suggesting are at the top of page 54. I'm just trying to get clarification that I'm reading the right thing here.

MS. ATACK: On page 54, we talk about both of the situations and the proposed changes to the regulations. We talk about how the fuel cycle facilities that are regulated under Subpart H, except those that are required to comply with Appendix B, perform management measures. We don't recommend any [rule] changes for those facilities.

Then down in guidance, we talk about the guidance that we plan to provide, and it goes on in a bit of detail as to what the staff believes we will provide as part of the guidance. It goes into 55 as well.

MR. MURRAY: Okay, well, the only other comment I would make is I hope everybody knows that typically management measures when they're applied to these types of procured items happen when they're put

into service, when they're installed. They don't always happen when they are procured or received. They happen -- the functional testing and other things as these component items is obviously placed into service.

So, I don't know if that was obvious throughout the whole document, but that's just one point I'm trying to make.

MS. ATACK: Thanks, Scott. I've mentioned that a couple of times verbally but as we move into the guidance preparation that will be something that will be very important to make sure we continue to emphasize is that the functional testing and the in service performance are a big part of the dedication process.

MR. MURRAY: It's a little different in I think the true definition of dedication in this sense. And the other point is some of these components that can be IROFS for different accident sequences may or may not be a basic component in that particular accident sequence.

In other words, the same thermocouple when applied over here may not be a basic component, but when it's applied over there because there's other controls or other reasons, it is a basic component. So, that's

why it is important to understand that the management measures, if they're being used in lieu of dedication, would not necessarily be the same even though they're both IROFS in two different places.

One place it might be a basic component. In another place it may not.

MS. ATACK: Very true. Thank you for that comment, Scott.

MR. MURRAY: Thank you.

MS. ATACK: Any other --

OPERATOR: No further comments.

MS. ATACK: Okay, great. So, let's move onto Section E, which is the definition of commercial grade item. This is probably the only part of the proposed rulemaking that the fuel facilities are genuinely happy about. So, I'm pleased to speak about this set of slides.

On slide 121, we cover the existing regulatory framework, and what you find in the definition of commercial grade item that's provided in the current version of Part 21 that is in use right now is that it's very prescriptive.

Commercial grade item for facilities other than nuclear power plants includes a lot of

requirements. The item is not subject to design or specification requirements that are unique to those facilities or activities. The item has to be used in applications other than those facilities or activities, and the item has to be able to be ordered from the manufacturer or supplier on the basis of pre-existing specifications.

So, in order to find a commercial grade item for fuel cycle facilities, it has to be something very straightforward that you can do a Google search and order from a supplier. They've already got to be making this for multiple users, and it can be overly confining for fuel cycle facilities, which, as we've already discussed, have very specific needs in terms of some of the items procured for their facilities due to their unique nature.

The regulatory problem, which I kind of let the cat out of the bag, is that the definition is very prescriptive as currently written. The commercial grade item definition that is in use right now restricts commercial grade items to those that are generic in nature, and fuel cycle facilities have had some difficulty in finding components that can be dedicated as commercial grade items due to the specific needs of

the facility.

Having such a limited definition of what can be deemed a commercial grade item has resulted in procurement challenges and the need for licensees to seek the exemption requests that have been mentioned previously during the presentation.

So, the proposed change to the regulations is changing the definition, and this was discussed during the morning session. The proposed definition the staff is providing would be simply that a commercial grade item is an item that is not a basic component. That would relieve all the prescriptiveness as to what can be dedicated as a commercial grade item.

That would allow items that are specific to facilities and users to be dedicated. That's the end of that section. Any questions on commercial grade item proposed changes?

I see none in the room. Do we have any on the phone?

OPERATOR: Robert Link from Areva, your line is open.

MR. LINK: Actually, I had a clarification question on the previous section, and then I have one on this one too. But apparently I prompted you to think

about some additional information not in the slides relative to -- and I think specifically you were speaking to those facilities that have already Appendix B programs, fuel cycle facilities and have some license commitments in that context.

I'm going to use the words you would expect under the proposed methods going forward. They would be - and I'll use the word grandfathered - in, under their existing commitments and requirements, and the new rule would not necessarily have to be proscriptively fulfilled.

MS. ATACK: I'm not sure if that's entirely accurate. The existing licensees who have certain provisions approved via safety evaluation report would continue to comply with the provisions of those approvals.

They would be subject to the new requirements in 21.71. So, I would expect from what I've seen in the amendment request would be that most of the provisions of 21.71 would apply, but where 21.71 is more prescriptive than something we've already approved, the licensees would default to that less prescriptive approval.

So, it is not that they will be using an

entirely separate set of requirements. It will be that they're complying with 2171 and where 2171 is more prescriptive than something we've already approved, then they would default to that less prescriptive requirement.

What I've seen would -- example would refer to the way that the technical evaluation performed as part of dedication is documented. So, that could be documented as part of a procurement package instead of in a separate technical evaluation for certain items. Examples like that.

So, they would be a little bit more specific in terms of what changes would be applicable to facilities that comply with Appendix B. Yes, there would be some cases where they wouldn't have to comply with the new provisions because they are grandfathered in, per se, because of existing approvals.

MR. LINK: Okay, I think that makes sense to me. There might be a scenario I'd perceive that a licensee that has those type of exemptions may review the outcome of the rulemaking process and choose to basically come in and say, "I don't need my exemption anymore."

MS. ATACK: That's possible. I think this

would be -- and there was also a comment from the audience while you were talking. I think this is probably something we would want to address as part of the statement of considerations with the rule to make it clear what is applicable.

But yes, if a licensee would prefer to comply with the rule as revised, they could at any time come to the NRC and say, "I no longer want this license exemption that has been approved or this condition, and I'm going to make a change to my program to bring it into line with the new provisions of the rule."

MR. LINK: Now I guess I want to move onto the last topic and maybe use an example just to make sure I'm completely understanding it.

I admit that the existing -- I guess interpretation would not allow -- and I'm going to use a pencil tank. As you know, we use geometry controls in terms of -- and as a passive IROFS in limiting the diameter of a tank to a safe geometry.

Yet that would not necessarily be a catalog item, and we would write a purchase specification to assure that obviously both materials are compatible with the environment to work in as well as in the context of the criticality issue to be of safe geometry and

diameter.

That's not a catalog item, per se, and under the -- I guess one person's interpretation of the existing rule, we couldn't commercially dedicate that. And you're saying that under your proposal, if it comes true, that could become a commercial grade item which we could dedicate, and then once we've satisfied all our management measures, then classify it as a basic component.

MS. ATACK: That is correct. You can give the next presentation, Bob. You've mastered it. Okay, do we have any other questions on that section? All right, that brings us to the final section of my presentation, which is Section G: the Clarification of Quality Assurance requirements for the conduct of Dedication for Facilities that are Subject to Appendix B.

I think we've already actually touched on this. So, I'll pace ourselves through it. The existing regulatory framework in the current definition of dedication as applied to power reactor licensees does include the requirement that the dedication process be conducted in accordance with Appendix B to 10 CFR Part 50.

However, there are no similar requirements to identify QA requirements applicable to dedication activities to other facilities that are subject to the requirements of Part 21.

So, that brings us to the regulatory problem: That the regulation as currently written doesn't provide a description within Part 21 or any associated guidance related to Part 21 to describe the QA controls that should be applied to dedication activities for nonreactor facilities.

Moving onto Slide 126, the proposed changes that the staff has recommended would be first for fuel cycle facilities regulated under Subpart H, and not subject to the requirements of Appendix B. We wouldn't make any changes to the rule.

The guidance that we already discussed previously would describe the link between management measures and dedication. However, for the fuel cycle facilities that are regulated under Subpart H and do have to comply with Appendix B to 10 CFR Part 50, those facilities as part of proposed rule changes would need to comply with Appendix B for their dedication activities.

That is the end of my presentation. Do we

have questions on the applicability of Appendix B for dedication for fuel cycle facilities? None in the room. Do we have any on the phone? That concludes my remarks. I believe that concludes our meeting, but I'll hand it over to our facilitator to wrap up.

MS. CLARK: I just want to thank everybody. We have had a very extensive and robust discussion today, and I can assure you that your comments and questions will help the staff as we move forward in evaluating our regulatory analysis for Part 21.

The transcript for this meeting will be posted on our website, and I think that concludes the meeting. Anything else? All right, thank you very much.

MR. HEATH: I just want to thank everybody that showed up today, and for those that are still on the phone. Again, my name is Jermaine Heath, and I'm leading the -- or project managing the rulemaking effort altogether.

So, if you have questions or comments, you can email me. You should have my information. I encourage you to subscribe to the Part 21 website if you haven't already. I don't know if it's on here.

If you just go to Google. Go to Google and

type in NRC vendor into the Google search box. The instructions are on the slide. You'll find a link to 10 CFR Part 21. When you pull up our website, they'll take you there, and then you'll see a page at the top, "Subscribe to updates."

Then anything we issue that is Part 21 related you'll get automatically, in addition to it just being put on our website. It'll come right to your inbox. So, my information is there on the slides. If you have any questions related to Part 21 or this meeting, get them to me. If I can't answer your questions between me and my colleagues, I'll find the right people.

I appreciate you coming. So, if you didn't get your questions answered, again the meeting is being transcribed. So, when that comes in, the staff will take time to go through all of the meeting questions and comments and we'll take those into consideration as we prepare the final reg basis, which we hope to go out some time in June.

So, thanks again for coming. Thank you. That concludes our meeting, Operator.

(Whereupon, the above-entitled matter went off the record at 4:18 p.m.)

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