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NUCLEAR REGULATORY COMMISSION

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PUBLIC MEETING ON PART 53 RISK-INFORMED,

TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK

FOR ADVANCED REACTORS RULEMAKING -- SUBPART I,

MAINTAINING AND

REVISING LICENSING BASIS INFORMATION, SECTION

53.1322 AND OTHER TOPICS

RELATED TO PART 53

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WEDNESDAY,

SEPTEMBER 15, 2021

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The public meeting took place via Video Teleconference, at 1:00 p.m. EST, Dennis Andrukat, Facilitator, presiding.

PRESENT:

DENNIS ANDRUKAT, Facilitator; Office of Nuclear Materials Safety and Safeguards

MARCUS NICHOL, Senior Director, New Reactors, Nuclear Energy Institute

WILLIAM RECKLEY, Technical Lead, Office of Nuclear Reactor Regulation

JOHN SEGALA, Branch Chief, Advanced Reactor Policy Branch, Office of Nuclear Reactor Regulation

NANETTE VALLIERE, Advanced Reactor Policy Branch, Office of Nuclear Reactor Regulation

P R O C E E D I N G S

1:00 p.m.

MR. ANDRUKAT: Hopefully, everyone can hear me okay.

My name is Dennis Andrukat. I'm from the NRC's Office of Nuclear Materials Safeguards and Security. Today I'll be filling in for Mr. Bob Beall, who is the lead rulemaking project manager for this particular rulemaking.

I'm serving as the facilitator for today's meeting. My role is to help ensure that today's meeting is informative and productive.

This meeting is a comment-gathering meeting. It's to encourage active participation and information exchange with the public to help facilitate the development of this particular rulemaking. The feedback that the NRC receives today is not considered a formal public comment. So, there will be no formal response to any of today's discussions.

Once again, we are using Microsoft Teams to support this public meeting on the Part 53 rulemaking, and we hope that the use of Teams will allow stakeholders to participate more freely during

the meeting.

Slide 2, please.

The agenda for today includes discussions related to Part 53, Subpart I, for Section 53.1322 titled, "Evaluating changes to facility as described in final safety analysis reports," as well as Section 53.1333 titled, "Evaluating changes to programs included in licensing basis information."

There will also be an open discussion of the other recently publicly released preliminary proposed rule language for this Part 53 rulemaking. It will be included with the section on programs, which is Subpart F -- excuse me -- programs under Subpart F, which is the requirements for operation.

We will also have a 15-break this afternoon. And please note that, due to the number of topics and the expected discussion on each topic, that the start times may need to be adjusted during the meeting.

Slide 3, please.

I would now like to introduce Mr. John Segala. John is the Branch Chief of the Advanced Reactor Policy Branch within the Office of Nuclear Reactor Regulation. John will be giving the opening

remarks for today's meeting.

John?

MR. SEGALA: Hi, Dennis. Thank you. Can you hear me?

MR. ANDRUKAT: Yes.

MR. SEGALA: All right. Great.

I'd like to welcome everyone to our Part 53 topical webinar this afternoon. The NRC staff appreciates the efforts of all stakeholders who have been participating in the Part 53 rulemaking effort over the past year and recognizes the significant commitment of resources a project like this entails.

The staff remains committed to developing a technology-inclusive, risk-informed regulatory framework in accordance with Commission direction. The staff continues its novel approach of releasing preliminary rule language to facilitate early stakeholder engagement.

Since our last Part 53 public meeting in June of 2021, the staff has focused on developing and releasing the preliminary proposed rule language for the remaining subparts and is optimizing our public meetings to be more topic-specific, to enable richer focused dialog on specific issues.

The staff continues to consider input from numerous stakeholders, the public, and the ACRS, as we evaluate changes to the preliminary rule language.

As we discussed during the May 27th and August 26th advanced reactor stakeholder meeting, the staff is developing options for technology-inclusive alternatives that do not rely on probabilistic risk assessment in a leading role to address stakeholder comments.

We plan to release the first iteration of the preliminary proposed rule language for all of the remaining Part 53 subparts and the technology-inclusive Part 50 alternatives over the next several weeks.

As we stated before, the preliminary proposed rule language will remain open for discussion, as the staff works towards providing the Commission a proposed rule.

As Dennis Andrukat mentioned, today's public meeting includes specific topics focused on conditions under which licensees may make changes to the facility, as described in Subpart I of Part 53, and required plant programs, as described in Subpart F of Part 53.

We look forward to having discussions today and hearing your feedback on these important focused topics.

This completes my opening remarks. Thanks.

MR. ANDRUKAT: Fantastic. Thank you, John.

I would like to introduce the NRC staff who will be leading today's discussion: myself, as the leading facilitator, and from the Office of Nuclear Reactor Regulations, we have Mr. Bill Reckley. We will also have speakers during today's meeting from the Nuclear Energy Institute as well, as you'll see later on.

Okay. If you are not using Microsoft Teams to attend this meeting, and you would like to view or have a copy of today's presentations, they are located in the NRC's ADAMS document database and on regulations.gov. And we have also placed a link to the slides in the Teams chat window, as I will do momentarily. Now the Accession No. for the slides, today's presentation, is ML21252A, as in alpha, 124. That's ML21252A124.

In addition to the slides, I'll give the

ADAMS Accession No. for today's Subpart I discussion table. That's ML21243A, as in alpha, 076. So, that's ML21243A076.

Okay. Slide 4, please.

The purpose of today's meeting is to exchange information, answer questions, and discuss the Part 53 rulemaking. This is the first of a series of public meetings where the NRC staff will discuss specific topics related to Part 53 rulemaking, as John Segala just mentioned. As such, today's meeting will focus on the preliminary proposed rule language for Subpart I of Part 53.

For those people on the phone -- I'm about to get to this -- or on Teams, if you haven't done so already, please go ahead and mute yourself or hit *6 to mute.

Okay. Let's see. Today's meeting will focus on the preliminary proposed rule language for Subpart I under Part 53, again, Sections 53.1322 and 53.1333. These are related to the evaluation of plant changes. Again, I will place a link in the Teams chat window for these ADAMS Accession Numbers.

In addition, there will be an open discussion for the other preliminary proposed ruling,

which that has already been made public.

Like I said before, this is a comment-gathering public meeting, which means that the public participation is actively sought, as we discuss these regulatory issues. However, because of the number of attendees, we may need to limit the time for an individual's question or discussion on any particular topic to make sure everyone has a chance to participate. And after everyone has had a chance to ask their questions, we can circle back and allow folks to ask additional questions, as we have time.

Okay. Yes, we are using Microsoft Teams, as most of you can see. We are using this to facilitate a workshop format. And so, the number of formal presentations and corresponding number of slides have been reduced to, therefore, allot more time for the open discussion of these various topics.

This will also require us is ensure our phones are muted when we are not speaking and to do our best not to speak over each other.

Now, of course, to help facilitate the discussion during the meeting, we request you utilize the "Raise Hand" feature. This is at the top of the screen next to the three dots. The staff will then

call on an individual to ask their questions, and then, we'll proceed with the discussion.

Okay. You can also use the chat window to alert us that you have a question. However, please do not use the chat window to ask or address questions about the rule. The chat window is not part of the record, but you can use it logistically to let us know that you have a question.

Okay. During the meeting using the Teams bridge line, you may not have access to all of these features. So, if you would like to ask a question or provide a comment, you will need to press *6 to unmute your phone to let us know that you have a question, and when you're called upon to, then, ask the question and proceed with the discussion. Of course, once we're done, we would ask that you press *6 again to mute.

If there is a particular topic you would like to discuss, please send an email after the meeting for future discussions and for consideration in the future public meetings. And so, in that case you can send it to Bob Beall, which is just bob.beall@nrc.gov. He would be the one to process that request.

This meeting is being transcribed. So, in order to get a clean transcription and to minimize distractions during the meeting, again, we ask everyone to please mute their phones when they are not speaking.

We also ask that you identify yourself and your affiliation at the beginning of your chat/discussion.

A summary and transcript of today's meeting will be publicly available on or before October 14th of this year.

And finally, this meeting is not designed nor intended to solicit or receive comments on topics other than this rulemaking activity, and no regulatory decisions will be made at today's meeting.

Please note that, towards the end of the presentation, there are slides containing the acronyms and the abbreviations expected to be used during today's meeting, as well as a set of backup slides that contain additional information about this Part 53 rulemaking.

Okay. Billy, if I can have slide 5, please?

Okay. And with that, I'll turn the

meeting over to Mr. Bill Reckley to start today's discussion, starting with the Subpart I for Part 53.

Bill?

MR. RECKLEY: Okay. Thank you, Dennis.

So, Subpart I is related to maintaining and revising licensing basis information, basically, once you move into the operating phase of the life cycle.

We haven't talked about if for a while. Early on, when we were laying out the structure of Part 53, we mentioned that we envisioned Subpart H would be primarily aimed at the initial licensing activities and Subpart I would relate to maintaining that during operations, largely by the licensee for the operating units.

So, it's, basically, broken down, Subpart I, into those parts of the licensing basis information that requires NRC approval. Those things would be like regulations for which you get an exemption, technical specification or a license condition, for which you would get an amendment. Those processes were either described in other sections, such as Subpart A for exemptions, or within Subpart I, they basically have just carried over the processes, well-

established processes, from Part 50. And so, we weren't really planning to talk about them today. The license amendment process in Subpart I is basically the same as the regulations in 60.90, 91, and 92 for the current operating fleet in terms of the process.

But one area that we did want to get some feedback on is the control of the Safety Analysis Report and the evaluation of changes to the Safety Analysis Report and the criteria to decide if a change warrants NRC prior approval. So, that's the equivalent of 50.59 for operating units.

We also want to talk a little about the control of programs, but the focus will largely be on the equivalent of 50.59 within Subpart I. And so, that is Section 53.1322.

Before getting into that, when we released Subpart I, the discussion table associated with this subpart, we tried to make clear that this iteration assumes a design and licensing process with what NEI calls a leading role for PRA. So, this is a design and licensing process similar to the Licensing Modernization Program that we endorsed in Reg Guide 1.233.

So, as John mentioned in his opening

remarks, we are looking for more traditional or deterministic-oriented approaches to design in licensing. As we develop those and roll those out, they would likely have a corresponding change control mechanism that would either by 50.59 or something similar to it, because it was developed for that traditional or deterministic approach; whereas, the sections we're going to get into in this discussion are new criteria that try to take full advantage of an LMP-type [Licensing Modernization Project] approach.

So, if we can go on, then, to slide 6?

What I'm going to do in the next couple of slides is just do the high level, and then, we'll talk -- I have a slide on each of the criteria to kind of look at it in a little more detail, and then, solicit discussions, especially interested in those who would be using an LMP-type approach, to see if these criteria make sense and they could envision how they would work once you go from initial design in licensing into operations.

So, 53.1322(a) lays out the change evaluation process and identifies when a change would warrant a license amendment.

So, the first one is if it involves a

change to a technical specification. So, that's the same as the current 50.59, and it just goes to the nature of tech specs being an appendix to the operating license.

The next five bullets are related to change criteria. So, these are the criteria that a licensee would consider as they make a change to the plant to determine if an amendment would be warranted.

So, the first one is it results in a change to the frequency of consequences of an event sequence previously deemed not risk-significant, such that it becomes risk-significant. And I have a slide where we'll talk about that.

The next one is that, if the event sequence was already considered to be a risk-significant sequence, then it goes to evaluate the reduction in margin. And as a starting point, the criteria selected was a 10 percent reduction in the calculated margins -- a good place to start, we thought. The 10 percent number has some relation to the historical implementation of 50.59 and the more than minimal changes that are in that language.

The third one is that it results in frequency or consequence changes to one or more

sequences, such that it impacts the cumulative risk and decreases the margins to the safety criteria in 53.220. So, these are remaining for now to be the NRC safety goal numbers.

So, a reduction in the cumulative risk of 10 percent compared to where a plant would currently evaluate itself to be, and after a proposed change, where would it be. And if the change would affect the cumulative risk and decrease the margin by 10 percent or more, then a license amendment would be needed, in accordance with this criterion.

So, then, we if we go on to slide 7, the last two of the criteria are:

The top bullet involves a departure from a method of evaluation, as described in the updated Final Safety Analysis Report, used in assessing the margins. And this is, again, a concept that should be familiar to most who are familiar with 50.59, in that this tries to make sure that we maintain a level playing field, that you don't start using a different analytical tool, and thereby, say the margins are not reduced, but that is resulting from the change in the evaluation method, not an actual evaluation of the plant change. So, that's the reason for this

particular criterion.

It goes on to say, which is, again, consistent with the guidance for 50.59, that if the evaluation method has been previously approved by the NRC, or it's endorsed in an NRC -- it's included in an NRC-endorsed consensus code and standard, that, then, you could use the departure -- then, you could use the newer evaluation method to evaluate the plant change.

Then, the last bullet or last criteria is that, for those licensees which we would consider to be probably many, if not all, if they're using an alternative evaluation criteria, as described in Subpart C, then the evaluation of the change would be related to the margins between where the event sequences are analyzed and to the alternate evaluation criteria. So, again, that might be a little vague. I have a specific slide with a figure that, hopefully, will make that more clear.

Then, the last two bullets, again, consistent with current Part 50/Part 52 that really are evaluating changes since the last submittal of the updated FSAR. There's another part in Subpart I that maintains that two-year updating frequency.

And then, the last bullet simply, again,

consistent with 50.59, if there is another evaluation required by NRC regulations, then, for a particular item or assessment, then you would use that assessment. And historically, those have been in various sections or paragraphs within 50.54, for example, that we have specific change control mechanisms for quality assurance, emergency planning, security. Within 50.55, you have specific changes for relief from the ASME Code.

So, go to slide 8, and I'll start to talk about the specific criteria and how we would envision it working. And then, again, this is really intended, then, to support a discussion at the end of this, again, with a focus on those that would be using a risk-informed or PRA-centered-type approach. And since the LMP exists, I am using it within the examples of how that would work.

So, again, the first criterion is it does not result in a change to the frequency or consequences, such that an event sequence previously deemed not risk-significant becomes a risk.

So, going back to Subpart C, we did, on the last or the third iteration of Subpart C make some conforming changes. And the first one is highlighted,

that as you evaluate licensing basis events, the previous iteration of B and C had called out the safety criteria of 210 and 220 for design basis accidents and for other LBEs, and had called out, basically, either the siting criteria, the 25-rem number, or the QHOs, as being the safety criteria.

What was lacking in that, in the first and second iterations, was that, when you're looking at each licensing basis event, there has to be some criteria to judge each event. And so, we did clarify in this last iteration of 450, paragraph (e), that that needed to be defined. Whatever methodology you're using has to have an evaluation criteria defined for each licensing basis event.

I think that was clear. We didn't think that was a dramatic change. It was a clarification. It remains consistent with LMP, as it's described in NEI 18-04 and our Regulatory Guide.

Then, the next highlighted section is something we added, and we added it specifically because, as we looked at the integrated approach over the life cycle and developed Subpart I, if we have an evaluation criteria under Subpart I where we want to take advantage of the judgments that need to be made

in terms of whether an LBE is risk-significant or not, then you need something in Subpart C to actually require that the methodology include a provision for determining whether an LBE is risk-significant or not. And so, that sentence was added to 450(e) at the end there, that the methodology used to identify and analyze LBEs must include a means to identify those sequences deemed significant.

So, how would that, then, translate using the LMP as example? The LMP already includes a definition for risk-significant LBEs. It's the two orders of magnitude from the frequency consequence target. So, that's the hashed area on this figure.

And so, if one were using LMP, then this evaluation against this criterion is shown in the red there. Assuming you have an LBE that is outside of the risk-significant region, this criterion would say, if you make a plant change and it influences either the frequency or the consequence of that sequence, such that it moves into the risk-significant region, then, under this criterion, that would be a basis for saying that change warrants a license amendment. So, that's the first criterion.

Going to slide 9, the second criterion,

using the same example and using the LMP risk-significant region -- again, two orders of magnitude from the frequency consequence target -- this criterion would, basically, lay out that, if you have an event sequence that is within the risk-significant region, then the criterion is related to the margin between that sequence, as it's been evaluated, and the frequency consequence target. And a 10 percent number is used. Again, it's a different number than 50.59, but it has at least a history and a bit of consistency by using a 10 percent margin reduction as the evaluation criteria. So, that's shown in this figure, again, on the assumption that you already had an event within the risk-significant and you're assessing margins.

And just as a reminder, when we're looking at these, we're not only looking at the event sequence mean, but we're also looking at the uncertainty bands. That's what the lines surrounding the red dot are intended to represent in this example, are the uncertainty bands. And an event sequence is considered to be risk-significant under LMP if the 95 percent confidence level is within the shaded area. So, that's the second criterion.

The third one, if we go on to slide 10, relates to cumulative risk. And so, it, basically, is another assessment of a plant change and whether the change to the frequency or the consequences would be such that it would affect the margins to the QHOs, which are the criteria under Section 53.220. And again, we used the 10 percent reduction in margin.

The second block here is just a reminder of what 53.220 is in terms of the current iteration that we're on for Subpart B. Those numbers are intended to be consistent with the QHOs, the quantitative health objectives.

So, then, we can go on to the next one, slide 11. Again, this is just trying to make sure that an evaluation of a plant change is done where you're actually evaluating the change to the plant or the procedure, and not influencing the evaluation of the plant change by introducing a new analytical code or other method of evaluation. So, again, the language we picked for paragraph iv, and you can compare it to the eighth question under 50.59(c) and see that it's meant to be a corresponding requirement from 50.59.

So, then, we can go on to slide 12, which

is the last criterion. And this one, we can talk about it a little bit. We've had some discussions about 53.470 and the application of analytical safety margins to operational flexibilities, but it's not clear to me, anyway, that people have always understood what it was we were talking about.

So, the criterion is that, for those that would be using an alternative -- and so, in the figure, the bright, dashed, red line is at 1 rem. And 1 rem is used, for example, in the emergency planning space for possible consideration of an alternate emergency planning zone. That's the rulemaking currently underway. We used it as a proposal to provide alternate guidance for siting in regard to 500-people-per-square-mile out to 20 miles that's currently used.

It may be used in other areas, including staffing discussions that we'll get into over the next few weeks, but there may be a number of reasons that an applicant or a designer would want to say that the dose -- that we're going to establish an alternative limit and use those margins to justify operational flexibilities, such as a reduced emergency planning zone or a siting alternative, or the other examples I

gave.

So, the second blue box there is just giving the current iteration language from 53.470 on the application of analytical safety margins. It, basically, lays out that an applicant can propose such an alternative.

And then, the majority of the requirement is just to make sure that, upon doing that, that the analytical margins are maintained over the life of the plant, so that an argument for something like a reduced emergency planning zone is not degraded over the years by plant changes or other factors. So, it's both the adoption of an alternate criteria, and then, the maintenance of that. Because once adopted, it becomes part of your licensing basis and part of the evaluations you would need to do.

So, the specific criterion under (v), again, it's a margin reduction assessment. And for this particular one, we used 25 percent, saying you would look at event sequences, and if the proposed plant change, procedure change, other things being evaluated, caused an event sequence to move closer to your alternate criteria, again, such that it reduced the margin by 25 percent, then that would be a reason

to trigger a license amendment for that particular change.

If we want to go on to slide 13.

So, those criteria are the primary reason we wanted to have this topical meeting; basically, hear from those, again, especially interested in those that might have used the LMP or as a tabletop or TICAP [Technology-inclusive Content of Application Project] as a tabletop. So, you would be familiar with the numbers. You would be familiar with your margins and could provide some insights as to the use of these kind of criteria.

But, before opening it for discussion, I'll just kind of finish out this section, 53.1322. It does include paragraph (b) that lays out the process by which a departure from a design certification would be pursued, if the operating license or the combined license is referencing such a design certification. And again, this is largely consistent with the existing requirements of Part 52.

Basically, if you're going to change the information as it's certified or that is included in the certification by the rule, then you're going to need to get a license amendment and an exemption from

that rule. Then, we want records to be maintained of all departures and when FSAR updates are updated, to flag those departures.

And then, the last bullet on this slide is just we're still developing Subpart G on decommissioning, but just the understanding that, once you've moved into decommissioning, you're going to be doing a different assessment, and just like currently, you're going to ask different questions than those criteria that we talked about on the previous slides.

So, I think, Billy, if you can go to 14.

Then, paragraph (c) is the recordkeeping part. Again, this is consistent with current requirements, expectations. Evaluations of these changes to the facility or the procedures have to be made. They have to be documented. There has to be a record produced, and then, reported to the NRC, just like 50.59 changes are currently reported. And we maintained 24 months as the reporting requirement.

And then, the last bullet there is just record retention. Again, the same as currently in the Part 50 corresponding regulations, and 50.59, 50.71, and other references.

So, if we go to slide 15, I'm going to

really kind of go back to open up the discussions. But, just maybe as a warmup, Subpart I also talks about evaluating changes to programs. And I know we're going to have a discussion of Subpart F's listing of programs, but, currently, within this iteration of Subpart I, the same evaluation criteria are listed in terms of the programs, but we included this note in the discussion column of the table that it's not clear that the questions are the best way to address changes in programs. It would provide a consistent set of questions for evaluating licensing basis information, be it in the SAR or in program documents, but the program documents are somewhat different, and that's reflected in the first couple of additional change criteria that are included in this iteration of Subpart I.

One is some of the programs are directly related to regulations. And so, one reason for needing NRC prior approval of a change to a program is if the change to the program actually deviates from an underlying regulation, in which case you would need an exemption.

And there's also Item 3. There may be additional change criteria that are included within a

regulation. Those are currently like the ones we put in 50.54 now. For certain programs, there could be, likewise, some provisions that would be put in maybe the administration section of tech specs. And so, we added Item 2 and 3 to address that.

And then, the rest of the criteria are the ones we just talked about. But, again, either right after we talk about the change to the FSAR and the five criteria or, if it makes more sense, since we're already going to be talking about programs, we can talk about it then after NEI gives its presentational programs.

But, for now, then, we can go to slide 16.

I, basically, just wanted to open this up and get any questions, observations, and again, really would love any insights that might come from anybody that's tabletopped LMP in terms of the criteria and how they think they just might work.

So, Dennis, I'll kind of hand the MC role back to you.

MR. ANDRUKAT: Sure, sure. Thanks, Bill.

So, we'll have some general discussions. I'll open this up here in a second, and then, following some of these general discussions on the

Subpart I that Bill just talked about, then we'll move on to -- NEI has some presentations on this as well, some of their thoughts.

Okay. So, opening up to general discussion. For now, attendees may use this time to ask their questions, of course, but please use the "Raised Hand" feature. And again, please do not put your questions straight into the chat window. That's not part of the record. And as you raise your hands, I'll go ahead and start to call on you.

And I see the first one, we have Keller.

So, please go ahead.

MR. KELLER: Yes, this is Mike Keller with Hybrid Power Technologies. Can you hear me?

MR. ANDRUKAT: Yes, sir.

MR. KELLER: Okay. As a general remark, it strikes what the staff is attempting to do is overly complex for a high-level document involving what are, essentially, material changes to the FSAR. I think it would be more practical to just use a broad clarification, using the 10 CFR 50.59 language and put the details in some form of guidance document. That provides more latitude for what are pretty in-depth requirements, and it also allows for a way to deal

with those licensees that may use a PRA approach that isn't as rigorous as what you're planning.

As a specific remark, the NRC staff continues to equate the AOO and DBE requirements, when the AOOs are, obviously, vastly less risk-significant. What I would suggest is reduce the margin to, say, 5 percent for the AOOs with less strenuous administrative requirements.

That concludes my remarks. Thank you.

MR. ANDRUKAT: Thank you. And thank you for introducing yourself and your affiliation. That's a good reminder for the rest of us.

So, Bill, I didn't know if you wanted to say anything in addition or to respond. So far, I don't see anyone else's hand up.

MR. RECKLEY: We can move on, then, to the slide and let NEI talk about their slide, and then, kind of continue, then, to give people an opportunity, if they want to think about it for a second.

MR. ANDRUKAT: Sure, sure. Okay. So, at this time, we'll jump over to slide 17 and turn it over to NEI's Marc Nichol. So, he'll give a short presentation relative to what was just discussed here as well.

So, Marc, are you there?

MR. NICHOL: Yes. Thanks, Dennis. Can you hear me?

MR. ANDRUKAT: Yes, sir.

MR. NICHOL: Okay. You can go to the next slide. This is our only slide on this.

I do want to say that this is not an NEI position. What we've done is we've discussed it with our members and we've collected a bunch of thoughts and questions to facilitate the conversation. So, don't take these as meaning it's the industry's position. Just take it as sort of one-offs to facilitate conversation.

So, I'll walk through these and help to explain them. And the presentation that you just gave, Bill, was actually informative and will help maybe shape some of these in different directions.

So, I'll start with the area of just general observations. These were intended to be somewhat objective and not intentioned to direct the direction of it.

So, the first one, it's very quantitative and should appeal to the PRA-intensive approaches. So, Bill, you had said that NEI's has called it the

leading approach. Thank you for the attribution. We didn't come up with it. But we're starting to call it a fundamental approach, which is, basically, the PRA forms the foundation of the safety case, deterministic analyses, to help to complement that, in opposite of traditional, which I wouldn't call traditional approach deterministic because there are risk-informed traditional approaches. It's traditional approaches use the PRA in a confirmatory role, instead.

So, within that, I think what the NRC is doing is a good endeavor to try to find a change control process that better aligns with LMP and TICAP. It's the only foundational PRA approach out there right now. So, to come up with 50.59 approaches that work better for it is a good thing.

There was an observation that it wasn't clear what the benefit was. Functionally, it wasn't so different, and functionally not being different is not a bad thing. It shows the consistency there with what 50.59 has done.

I think, Bill -- this is my personal observation -- I think your presentation helped to identify where there are some noticeable benefits for this. And I would welcome others, especially those

familiar or interested in LMP and TICAP to say whether they would see this or not.

But, particularly, the way that you've defined, I call it, "the shadow zone," that risk-significant zone; that if you're outside of that far to the left, and if the change you're making doesn't bring you from non-risk-significant into that risk-significant zone, you can make those changes.

I think that enables a lot more flexibility for the licensee that would use this type of foundational PRA approach and flexibility that is rightly due, because these are of such low safety significance that they should be able to make those changes. So, I would personally say that I think that that's a noticeable benefit, based on understanding it a little bit better.

The next bullet, "proposed change criteria," confusing, difficult to interpret, and that goes along with needs significant on how to explain how it works. They sort of go hand-in-hand.

Your explanation helped to get to the concept. So, I think, at least personally, I understand your concept a lot better than just reading the language when it came out. It will require

guidance. It will require a lot of work to develop how that guidance would come out and be implemented. That's not a suggestion not to do it. I think there is a reason to go through and develop a more PRA foundational change control process, but it is to say that we all need to be mindful that this is going to be a great deal of effort in developing guidance, so we don't underestimate that.

The final one, under "General Observations," "10 percent change criterion," consistent with the 50.59 guidance. In fact, I think they even say 10 percent change.

However, the regulations in 50.59 say more than minimal, and a couple of things here. The "more than minimal" provides more flexibility than 10 percent, because, one, it's deterministic in nature, or I'd say it's not quantitative. And so, what "more than minimal" means could mean 10 percent or it could mean something else, if you need to evaluate it on a qualitative or deterministic basis.

That would be true even under an LMP and TICAP, where some of the elements are deterministic, especially inputs can be. Or if somebody wants to use LMP and sort of bound it at one place or another, and

therefore, they don't use strict quantitative, but they just assume some probabilities or use some deterministic. Then, that 10 percent might have some impact there.

The other point is -- I believe the Commission actually pointed it out one time on 50.59 -- that the regulation itself allows more flexibility than the guidance NEI 96-07. So, we should consider whether putting 10 percent in the rule reduces some of that flexibility. I know it gains clarity, but, then, again, that 10 percent clarity comes in guidance. So, we should consider that, whether it makes more sense to have 10 percent in guidance or in the rule.

Next on questions -- I think you've answered what a 10 percent decrease in margin means, and it's the F-C curve, and that helped a lot. But there is a question on, how is it measured? Is it based on the mean value? Is it the upper uncertainty band? The PRA, obviously, has a lot of complexity to it. It's not just a single point. So, getting insight on that, if you're able.

I'll just go through my comments, and if you're able to respond to any of these at the end, that would be appreciated.

Another question is, well, how are design basis accidents and defense in-depth addressed? We didn't see it. If it doesn't need to be addressed, that's fine. We were just wondering if the NRC had thought through that and had any feedback on how you saw those two elements within the LMP and TICAP structure being addressed.

The "criteria apply" -- here's potential concerns -- the "criteria apply to all risk-significant licensing basis events" -- AOOs, DBEs, beyond design basis events. 50.59, typically, generally, applies more to the design basis aspect of the plant. That's in the FSAR. So, including AOOs and beyond design basis, it sort of expands the scope of what the change control process deals with.

The fact that you're already assessing it to the QHO, you're already, in that cumulative way, you're already addressing all of those. So, would it be possible to limit the 10 percent criteria and those sorts of things just to the DBE zone, would be one question.

This may be a question. So, there's hundreds and thousands of event sequences. The way the rule language reads, that you would evaluate

changes to every single event sequence against that criteria. Those collapse into LBEs. It would be much simpler if you just compared the LBEs. There would be a lot less work at least in terms of administrating the change control process.

I think you addressed the more than 10 percent change on low frequencies, the way you described it earlier.

And I think you addressed this, too, to an extent. Margins to metrics in LWRs are different from those in advanced reactors. When you explained that the evaluation criteria needed to be applied in, I think it was 53.450, I think that will be the way for developers to identify what they are specific to their design. I think that's just something that we had missed earlier when you had done that.

The last point is, in your criteria on methods of evaluation, you added a term "used in assessing margins." And that's not in 50.59. It doesn't seem consistent with how 50.59 is applied, methodologies, and they define it more as "calculational framework used for evaluating behavior or response of the facility."

When I look at "used in assessing

margins," and I think about going through your explanation and how LMP and TICAP work, I wonder if this is unnecessarily, or maybe even inadvertently, bringing in a large scope of the methodology that is developed to meet NEI 18-04, including the extent of the PRA. The changes to the PRA may have to now be screened under 50.59 or evaluated, if they meet the criteria.

So, I know that was a lot to lay out. I figured it might be easier just to do that, and then, you can provide any thoughts on areas, where you would like to.

MR. RECKLEY: Yes, thanks, Marc.

And just starting with your last point, we'll look at that language. Basically, when we said, "used in assessing margins," it was just the calculational tools. So, we didn't want people -- just like 50.59 does. But LMP does have within it the concept of margins a little more than the traditional approach does. But we'll look at that language. It wasn't really intended to broaden the scope in comparison to what's done now.

And I agree with you that the guidance will be critical. Because the intent here would not

be to dramatically increase the workload associated with evaluating plant changes. And the thought is that most plant changes would still be evaluating using engineering judgment, just as they are now. Very few 50.59 evaluations include going back and rerunning a Chapter 15 code to see whether the margin decreased by 10 percent or more, or more than minimal. Most of that is just done by looking at it and saying this change is not going to have a dramatic impact on frequency or consequences.

So, the hope would be that that same type of assessment would be used here, with the engineering judgment being it's not going to change the frequency or the consequence of licensing basis events. So, agreeing with you that that would be laid out. That would be laid out in guidance.

The initial thought in regards to the bullet on DBAs and defense in-depth was that that was addressed, at least indirectly, in the criteria that we had, including, as you mentioned, the cumulative, the inclusion of a cumulative metric.

And for design basis accidents, the thinking is, under what we've done in Part 53, the design basis accidents are more directly tied to the

safety classification and the technical specifications, but they are also derived from the non-DBA licensing basis events. And so, the thinking was by including the measure of those other licensing basis events, that we wouldn't need to include a specific thing for DBAs. But, again, I would, if not today, at some point, ask the people who have gone through these exercises to let us know if that, if they see any issue with that.

Let's see. So, again, in regards to the event sequences and there being hundreds or thousands, depending again, the thought was not necessarily, although it would be available to people to run the PRA, but we thought most changes wouldn't require that.

Other parts of Subpart I are going to require that the PRA be updated; that the reports, in terms of the FSAR updates, are going to include a discussion of, overall, the plant changes that have been made and the impact of those changes on the events and on the cumulative risks. So, we think we have that kind of captured under the FSAR update provision.

I know, internally, that was a discussion,

and it comes up often whenever you talk about a change impacting specific event sequences or specific LBEs, as to how we're looking at the cumulative changes. And again, under the FSAR updating, I think we've captured that by including a requirement to report on any changes to the cumulative risk. That would be done anyway. I think that's consistent with the discussions underway in terms of TICAP, that that kind of discussion would be included in the FSAR. And if it's included in the FSAR, then it would be captured by the FSAR updates.

Did I miss any of the more significant ones that you thought you had, Marc?

MR. NICHOL: I think you got them all. I appreciate that. I've got a comment on programs I'll make in a second.

But you mentioned that you were expecting most changes would be evaluated under engineering judgment and not require an updating or reperforming, I'll just call it, the analysis, whatever calculation that might be. And I'd look to any others that may be 50.59 experts than I. But, just in my limited experience in applying 50.59 when I used to work for a utility, every change that we made that had to go

through 50.59, we actually reran the entire calculation that undergirded the safety basis. We just had to, and you had to update the FSAR, according to it, as well, if it required an FSAR change. Not that that's the end of the world, but just in case -- I could be misunderstood -- but just in case you're assuming that those analyses aren't being rerun, but if they actually are, just to make that point.

But let me make the comment on the programs, and then, we'll see if others have comments in this area. So, two comments on the programs.

I understand from your slide that the intent is that this would not duplicate a change process. So, let's just say you've got the security program, and the security program has its own change control process. This, I'll say, 50.59 equivalent change control program for programs wouldn't be a layer on top of that? You could just say, well, I can change it, based on the change control allowed in the security regulations; this doesn't apply.

When I read 53 -- what is that, 1333? -- it doesn't come across that way. You may want to check how it's worded. The way it comes across is that this would always apply, and that the fact that

you changed it under that would just be one condition for that. So, I don't think the rule language achieves what you were trying to get to, is my point.

The other comment is, I really have a question on, how do you actually apply it? And you even brought this up. So, these are very quantitative type of analyses, risk-based. And so, how do you apply it?

In my thinking about it, it may work very well for programs that control SSCs, especially, say, the reliability and capability targets of SSCs. It might be easy to apply to those. But I think it would be difficult, maybe not possible, to apply it to programs that primarily deal with human actions. And I'll just say, let's say, to give an example, the operator training program. I don't know how I could apply that to operator training and how you implement that program. That seems to be very difficult.

So, it's just something to consider, as you look at that. I understand your goal of trying to have one change control process for programs, and I think the goal is laudable, but you just have to think through how it might apply to different programs.

MR. RECKLEY: Yes, thanks. And as our

discussion column pointed out, we weren't convinced it was possible, either. But we don't have currently -- and this section could end up being the equivalent of -- multiple 50.54 paragraphs, right? So, we could have change control for individual programs, as is currently included in 50.54. And if that's the right way to go, that would be okay, but we were just kind of laying out and asking the question, and to be honest, having some of the same reservations you just expressed, that it's very difficult to do, to have a single set of questions to evaluate programs. So, thank you for the comment.

Dennis, anybody? Still no hands?

MR. ANDRUKAT: Still no hands. I'm not seeing anything in -- oh, Mr. Keller, it looks like you just raised your hand again. Go ahead.

MR. KELLER: Yes, I did. I think the Code of Federal Regulations needs to be broad in nature, and your guidance providing the details. You stated that you would hope that the licensee could use an engineering judgment, but I don't think what you're putting in the Code of Federal Regulations would support that. I think you need to have some flexibility built into the Code of Federal

Regulations.

That's the end of my remarks.

MR. RECKLEY: Okay. Okay. Thank you.

And again, going to Marc's point, at some point, all the plant changes do need to get rolled up and included in periodic updates to the analysis and the evaluations. And my experience might be more dated that yours, Marc, but I do think that, although they ultimately need to get rolled up and reflected in the analysis, that individual 50.59 evaluations would often just rely on the engineering judgment of the evaluator.

But, anyway, we had another question or comment?

MR. ANDRUKAT: Yes. It looks like Mr. Frank Akstulewicz.

Yes, if you could just give your name and affiliation, and go ahead and proceed.

MR. AKSTULEWICZ: Sure. Hi. This is Frank Akstulewicz, Terrestrial Energy. Just kind of two questions or comments.

One, as somebody who used to sit on a 50.59 violation review board, the more specific you make your criteria for evaluating the change, the more

detailed the expectation is from those that are doing the inspection about the quality of the demonstration that the criteria is met. So, there is a direct relationship there. And guidance isn't going to help that. So, that's my first comment.

The second is, I noticed in the chart that you showed the expansion beyond the range of the uncertainties around, I'll use the word, "event," not "the sequence," but the "event." So, how does the staff see dealing with broad uncertainty bands?

Because I'm going to guess that the uncertainty bands around some of these events are probably 30 or 40 percent either way. So, you said you're at 95 percent. So, that means you would have to change 10 percent beyond the 95 percent uncertainty band. So, your uncertainty with respect to the range for that particular event could be as much as 50 percent, using the example that I had? Or if you're inside, if you're saying the event changed 10 percent, but your uncertainty band is 40 percent, you've got nothing to worry about because you're still within the range of uncertainties?

So, would you like to take some time to kind of walk through that?

MR. RECKLEY: Well, I think the way it would happen is, typically, a plant change is going to affect the mean and the uncertainty bands would remain relatively the same. But, in terms of whether you're a risk-significant event or not does depend on the uncertainty bands. And if any part of your uncertainty band is entering into the region, that's a risk-significant event.

I guess, hypothetically, you could do a plant change that increases your uncertainty, and in which case if the change enters you into the risk-significant region, not because you changed the mean, but because you increased the uncertainty, you would, likewise, then, enter into the risk-significant region, and it would be a reason for an amendment.

So, really, if you just consider every licensing basis event as being the mean dot with a circle around it, because of the uncertainties in frequency and the uncertainties in consequence, any part of the circle that is entering into the risk-significant region, then it's a risk-significant event.

MR. AKSTULEWICZ: Thanks, Bill.

My question wasn't so much about -- that

helped -- but it wasn't so much about whether it pushes it into the risk-significant band. And I don't have the criteria up in front of me, but it's the second one, where the event changes by 10 percent, right? That wasn't anything that had to do with whether it pushed into the risk-important range or not. It didn't say that, if you're already in the risk-important range, then you're worried about the 10 percent change. It's just blanket, any 10 percent. So, for any percent, or a 10 percent reduction in margin, no matter where you are on the chart --

MR. RECKLEY: Yes, but, under the LMP, the margins are generally identified as being the 95 percent number.

MR. AKSTULEWICZ: I agree with you, but I think what we're arguing about -- it's semantics here --

MR. RECKLEY: Right.

MR. AKSTULEWICZ: -- is the rule and how somebody is going to read that rule 10 years after we're no longer doing regulatory stuff. And that's usually what happens. It is someone comes along and reads the language to be very specific and the rule, and then, the next thing you know, you have a huge

question in front of you about implementation. So, just that's a sensitivity that I had to the language; that's all.

MR. RECKLEY: Okay. Thank you.

MR. ANDRUKAT: Hi, Frank. Do you have any more questions? Just because I see your hand is still up, and I can lower it.

MR. AKSTULEWICZ: No. I tried to take it down. So, no, I don't have.

MR. ANDRUKAT: Perfect. Got it. Okay.

So far, I do not see anyone else. So, with that -- oh, Mr. Keller, go ahead.

(No response.)

Hey, Mike Keller, did you have another question for us?

MR. KELLER: Yes, I did. A hypothetical example, you know, you've got some rad waste system and you're going to change out, say, a gate valve with a ball valve, because the gate valve doesn't work very well.

The way this is laid out, are you going to get forced into a lot of administrative work dealing with that valve change because it affects the SSC, which may not, you know, like an engineering judgment,

say that's no big deal? I'm just uneasy that what you're creating may turn into an administrative nightmare for the operating crews.

I mean, I think you need to have some flexibility acknowledged at the higher-tier document, and perhaps in the guidance as well. I mean probably the guidance. That's just an observation.

Thank you.

MR. ANDRUKAT: Okay. I will go over to Mr. Marc Nichol.

MR. NICHOL: Yes, thanks.

So, just a question. This is more in terms, not on the content, but more on the path forward. So, obviously, we'll take back what we heard today. We'll develop some more thoughts and we'll send them to you in some form or fashion to help shape the rule language.

But I was wondering if you have a sense on what the path forward is for this, whether it is updating the rule language, which maybe doesn't need that much change? And more importantly, starting to work on the guidance, which I think is where a lot of these questions and details will be worked out. That will give more meaning to what's being proposed. Do

you have a path forward and a schedule on when those details might be forthcoming?

MR. RECKLEY: Not at the moment. I agree with you, and we are looking and continuing to talk. For example, the change control mechanisms are a discussion under TICAP, albeit that gets more complicated because that's addressing under the current framework with insights for us working on Part 53, but we'll talk to that group just to also kind of get a sense for their opinion on these criteria.

And then, we'll kind of enter it into the bucket of other guidance documents that we're going to need to prepare. As we prioritize those, you know, we're going to give the first priority to those that are needed for initial licensing, and the last priority perhaps, those that are related to decommissioning. And this one would fall in the middle, since it's supporting operations. That's just a very first thought.

MR. NICHOL: In that, I guess I do understand that the guidance won't be used until further on down the road, but sometimes people want to know what they're signing up for.

MR. RECKLEY: No, it's a --

MR. NICHOL: You don't want to be surprised at the end of it.

MR. RECKLEY: No. No, no.

MR. NICHOL: So, do you think there might be a draft version of the guidance accompanying the proposed rule or around the time when people are making comments on the proposed rule? That way, if people see the details and they say, "Well, wait a second. Now that we know how it works, it doesn't really look as good as we thought it did. We should make a comment that the NRC should allow for a 50.59 approach for those that don't want to use this," that type of thing.

MR. RECKLEY: Yes, we'll have to take that back, Marc. On our current schedule, I can tell you we won't have guidance done.

MR. NICHOL: Okay.

MR. RECKLEY: I will hedge that with, if there is any interest from others that are looking into how change control could work under LMP, and they're going to produce anything, then that would ease our burden, and maybe we could have something done. But if we don't hear about such an effort, this would not be what we could have done by the middle of

next year.

Okay. Anything else, Dennis?

MR. ANDRUKAT: No, I'm not seeing anything.

So, I want to thank Marc for his presentation, and then, Bill and Frank and Mike for their comments as well.

So, Bill, at this point, right, we're -- what? -- 33 minutes kind of ahead of schedule here? So, at this point, we would be changing gears to the next topic, but we would be taking a 15-minute break. So, do you want to continue with the 15-minute break now or just steam through?

MR. RECKLEY: No, let's get through the rest of Subpart I, and then, that will give us more time after the break, and we can talk about programs, and then, other topics, as people want to raise them.

MR. ANDRUKAT: All right. Okay. So, we're going to go on to -- what is this? -- slide 19?

MR. RECKLEY: Yes.

MR. ANDRUKAT: Okay. And I'll turn it back over to you, Bill.

MR. RECKLEY: Oh, I guess I was out of order. I thought there were more slides on Subpart I,

but I guess I had already gone through those.

MR. ANDRUKAT: Yes. Go ahead.

MR. RECKLEY: We can open it up, and I'll just go to Marc and say, do you want to start on the programs? Or we could, for a half an hour, just say, okay, we've released a bunch of other iterations, and right after the break we'll start into programs?

I'll leave it up to Marc.

MR. NICHOL: Yes, I think programs might be a little bit of a discussion. So, we might want to have that --

MR. RECKLEY: Okay.

MR. NICHOL: -- immediately after the break, yes.

MR. RECKLEY: Okay. All right. So, this we did want to have a very specific discussion on this element of Subpart I, but we have released a number of other sections. And we would use this as an opportunity to say, having looked at the other parts of Subpart I, Subpart H, Subpart J, the third iteration of Subparts B and C, all of those things that we've released in the last month or so, are there other questions, comments, or observations that people would want to make on other parts of the preliminary

language that we've released?

MR. ANDRUKAT: Mr. Keller, I see your hand is raised. Go ahead.

MR. KELLER: Yes. Your meeting notice and what it was going to entail, from our vantage point, literally just walked in the door like within the last couple of days, we're not really in a position to make any comments on what you've done. So, I'm thinking it may be premature to expect much feedback at this point in time. That's just a remark that I think needs to be placed in the record.

Thank you.

MR. ANDRUKAT: Of course.

So, Bill, I don't see, as of right now, I don't see any other hands raised.

Oh, Mr. Keller, did you have something else?

(No response.)

MR. RECKLEY: Okay, Dennis. Then, why don't we just take the break now?

MR. ANDRUKAT: Sure.

MR. RECKLEY: And when we get back, we'll do the NEI program discussion.

MR. ANDRUKAT: Fantastic. Okay.

So, at this point, we'll go ahead and take a break, and we will reconvene at 2:46 p.m. -- excuse me -- 2:47 p.m. Eastern time.

Okay, see you guys back in 15 minutes.

(Whereupon, at 2:32 p.m., the foregoing matter went off the record and went back on the record at 2:47 p.m.)

MR. ANDRUKAT: Welcome back. It is 2:47 p.m., Eastern Time. Everyone's back now and we are now on slide 22. So, this is the start of the presentation, NEI's presentation on Part 53 rulemaking programs.

So at this point, Bill, unless you have something else, I would like to turn it over to NEI's Marc Nichol to present their thoughts on the Part 53 programs.

So with that, Marc, go ahead.

MR. NICHOL: All right. Thanks, Dennis, and thank you for the opportunity for us to present on Part 53 programs. I know it wasn't a scheduled topic today. And the NRC in previous meetings has talked through Subpart F, which is where most of the programs lie. There are some others -- there are some in other areas of Part 53.

We wanted to present this. We've been evaluating programs as a whole that the NRC has been putting out and have been collecting a lot of thoughts, reflections, recommendations and wanted to share those with the NRC as input into your rulemaking efforts. So hopefully this will be helpful to you.

As I go through this if you want to interject, please do at any time. I'm happy to pause, answer questions, get your reactions. It's a large number of slides so we don't need to wait until the end to have conversations.

With that let's begin. So the first thing we did, we had noticed actually this came from realizing that there were a few programs that the NRC was proposing in Part 53 that we've never heard of before. And we thought well, what is that? And there were a few of them and we said well, let's take a comprehensive look at programs.

So a lot of our early discussion with the NRC was related to design and analysis requirements. We had a lot of discussion about how we -- we were concerned where the NRC might be doing things in design analysis which increased sort of the regulatory burden. The NRC had said well, you'll see benefit in

that in the operational space including administrative controls, which we're calling programs here. And so as we looked through that we wanted to see -- well, let's also make sure the administrative controls are trying to be as efficient as possible.

Even if you look at the current Part 50/52 and you were just to say well, let's bring over all those programs, we think you can do it more efficiently than that. Part 50 and 52 were developed over decades. Some of these programs were added on later and later and later. And so there's a good question about well, could it be more efficient if you started with a clean sheet of paper like Part 53? But the first step was to evaluate well, how do Part 53 programs compare side by side with Part 50/52 programs? And that's what the first three slides do here.

So this slide shows where we found Part 53 equivalents to programs that are required under Parts 50 and 52. So I'll talk about those here in a second. I do want to preface it, and I'll come back to this point later -- is that there are a large number of administrative controls that a licensee would do, or even the developer, anyone that's getting approval

from the NRC. And those administrative controls are bunched up into formal programs -- some of them are bunched up into formal programs that are required by specific regulations. They have to be submitted to the NRC, review, approved. They have to be controlled under Change Control Programs. But not all of those administrative controls. There's a lot of administrative controls that the NRC doesn't require, that doesn't -- but are important to complying with the regulations and administrative controls are -- even the licensee might call them programs, that don't need to be reviewed and approved by the NRC.

So the question; and I'll come to this as well, is well, what's that dividing line between what programs does the NRC have to require and they have to review and approve, and they have to have a process for change control versus those programs which the NRC doesn't. So that's sort of the distinguishing line that we're trying to figure out here, and the first step again was evaluating well, how does Part 53 programs stack up against Part 50 programs?

And what we found -- I think this is a set of 11. Some of these might have been condensed a

little bit. I've seen other lists that are more than 11. So it's not exact, but these were Part 53 programs with Part 50/52 equivalents and essentially these 52 -- these Part 50/52 requirements on the right side is the entire scope of programs under Parts 50 and 52 that are required by regulation as a specific program and need to have NRC review, approval, and control over the changes.

So within that there's a number of areas I think most people familiar with the regulations will identify, not in particular order, but there's initial startup testing, in-service inspection, maintenance repair. That would be ISI/IST I think is that one. No, sorry. I got it flipped around. That's the Maintenance Program. Maintaining capabilities. That's the ISI/IST. There's training in here, operating -- operations plans including emergency operations. There's fire protection, radiation protection, emergency preparedness, security, environmental considerations. I did forget to include the QA Program, but the QA Program is one as well, Appendix B.

I do note that the NRC hasn't come out with all of the requirements, specifically Subpart F

related to human actions. And it's possible that those might have programs imbedded in them, and so I put an asterisk on where -- if they did have programs where they might duplicate what's already here.

So this gives us a good snapshot that confirms that yes, of the programs that Part 50 and 52 require there's an equivalent in Part 53 and there's some general alignment. Now I'm not getting into the details. There may be significant differences in the details of how those programs look. That's not the purpose of this presentation. The purpose of this presentation is to make sure that the role of programs and the scope of administrative controls that the NRC has control over are either equivalent or they're appropriate. And certainly industry's goal is that they're efficient.

Let's go to the next slide, please. So with that once we get to aligning the 50/52 programs with Part 53, we have a whole bunch of other Part 53 programs left over that don't have a direct connection to Part 50/52.

So the first place I want to begin is programs that duplicate the Quality Assurance Program. So actually this is where I have it. I said it wasn't

on a previous slide. We pulled it out separately because what we noticed is two things: One, NRC took a different approach to the QA requirements in 53. They're scattered all over the place. The purpose of that I believe was to align design QA requirements in the design areas of the regulation and say manufacturing QA requirements in the manufacturing area of the regulation.

Not that it was a bad idea, but as we look at it and see how it's applied and how it will be implemented we have recognized that having all the QA requirements together, similar to what Part 50 does in Appendix B, is actually more efficient and clear and predictable. So one recommendation off the bat is put all the QA requirements together in Part 53.

But after that we look and we say well, you've got QA requirements and then you -- we've got others that are essentially programs that don't necessarily say they're QA requirements, but they're programs to do different things. But the purpose of those and the function and what they actually achieve duplicates what the QA Program is doing. So here's a list of those. There's design control assurance, construction/manufacturing, design analysis, design

control, and manufacturing. All of those duplicate what Appendix B would do. So if you put all the QA requirements together, you can eliminate all of these other requirements for programs that duplicate the QA requirements.

I would say it was -- the NRC had at least three, maybe four or five requirements for programs that did design quality control. And so it was very clear that the quality assurance requirements around design control are very important. And we would agree with that, but just having it once is more efficient than having it three or four times.

In our recommendation, if the NRC were to pursue it, which we think you should, to put all the QA requirements together, we think you should do it in a way that would allow flexibility, that somebody could meet those QA requirements through programs that comply with Appendix B that some developers have today and even some companies have

-- licensees and suppliers have today, but also allow the use of ISO-9001, other commercial QA standards.

Just a note for others that may not be aware, NEI is working on a guidance document on how you would be able to use ISO-9001 to meet Appendix B

QA requirements. And so if Part 53 QA requirements were similar to Appendix B, then that would be very easy to bring forward 50/52 compliance into Part 53 compliance.

And then finally we noticed that the NRC's QA requirements had some specific things related to non-safety-related, but safety-significant SSCs. If we look at 50.69 in Part 50/52, there's no specific requirements on what QA requirements should look like for that category. We do recognize that we have -- that the licensee would submit their augmented Quality Assurance Program to the NRC for review and approval, but there's no specific requirements for the standards that that program has to meet. It's determined based on what's appropriate for the risk significance. So we would encourage the NRC not to have specific requirements related to the standards of QA for non-safety-related, but safety-significant.

Next slide, please? The next set of Part 53 requirements didn't have a Part 50/52 equivalent. They didn't fall in the category of being related to quality assurance. Many of them do duplicate other programs. Some of them do not duplicate other programs, but we just didn't see why they would be

needed in Part 53. So some of these are -- well, these are listed here. I'll go through some of these.

53.700 and 53.800 are really purpose statements. And I'm not saying that it's not helpful to have purpose statements in the regulations. These are the first regulations in a subpart, so it is helpful to understand what that subpart is doing, but they read as sort of broad and open-ended requirements that could be used say for a NRC reviewer to say well, how did you meet that requirement?

I think the NRC has revised one of these general-purpose statements before that basically says this requirement is met by meeting all of these other sub-requirements so that it becomes much clearer what is intended by that requirement, or just to make it a statement that says the purpose of this subpart is X. So that's more of a way of phrasing requirements could address that one.

50.3850, Integrity Assessment Program. In parts of it duplicates the Maintenance Program, ISI/IST technical specifications. So it's not needed because it duplicates those. And then it also -- it effectively establishes an Aging Management Program from day one. Aging management is really applicable

to the license extension portion of things, so it would be a dramatic departure from the paradigm under Part 50 and 52 on how aging management is addressed.

There's three requirements related to Facility Safety Program, the criteria and the plan. This duplicates a lot of other programs. It codifies the periodic safety review, which the agency has policy not to require periodic safety reviews, and it has some provisions we think would circumvent the backfit protection.

I know this has been -- a Facility Safety Program was a brand new idea under here. We've been trying to evaluate it for a long time. We've asked the NRC to explain what the benefit would be and how it would work. We haven't seen what the benefit is. Given that we have some significant concerns on the things that it would be that would be undesirable and given that we don't have a lot of time left in this rulemaking, we think that the time to consider the Facility Safety Program is behind us and we should move on without it.

The Criticality Safety Program is -- criticality is under 50/52. There's no requirement for a Criticality Safety Program that the NRC has to

formally require and approve. I know that even under the 70.24 that -- so within that we think this could be better addressed by looking at creating a criticality requirement more similar to 50.68, rather than more similar to 70 -- I think it's 70.24. So that could be a way of addressing that one.

Construction and manufacturing organization and procedures. It's really not necessary for the NRC to approve the organization and plan for construction and manufacturing. It is not clear whether the NRC -- maybe they intended this just for a manufacturing license, and under that maybe we could discuss further on whether it's appropriate because the manufacturing license doesn't bring in some things that a construction permit operating license or COL bring in, but the way it's written I think that part of the regulation. Those requirement, the way they're written, they imply that they're applicable to construction permits, operating license, COLs, which for those at least this wouldn't be necessary and has no Part 50 and 52 equivalent.

The PRA Maintenance Program, it's really not necessary for the NRC to approve the controls for updating the PRA. There's a requirement for updating

the PRA. We're not talking about that. What we're talking about is the controls for updating it. It doesn't have a Part 50/52 requirement for submitting that program to the NRC. We don't know why the NRC is asking for it here. We don't think it's necessary.

And then finally the Human Action Performance Program, which we think duplicates training and other operational programs related to performance of human actions. Again not necessary.

So there's a number of programs here that the NRC has introduced we just don't think are necessary. All of these that are listed on this page, we would recommend the NRC deleting those requirements because they don't add anything to improving or enhancing reasonable assurance of adequate protection, but they do impact the industry quite a bit in terms of the level of effort to maintain these programs within the NRC oversight of them. So that would be our comment en bloc on those.

Before I move onto the next section, which is more of our ideas and recommendations for moving forward, are there any thoughts from the NRC on any of the evaluation I just went over?

(No audible response.)

MR. NICHOL: Okay. No worries. But you did give me a chance to take a drink.

MS. VALLIERE: Actually, Marc, I just had one question for you. This is Nan Valliere in the Advanced Reactor Policy Branch at the NRC. I just want to make sure I understand your position related to programs, the general position.

So you mentioned that NEI is assessing programs in Part 53 by asking -- I heard three questions: Are they equivalent, appropriate, and efficient? So is it NEI's position that the number and type of programs that are required in Part 53 as related to existing regulations -- that they should be the same whether you're developing the safety case using the PRA in a leading role as we've been outlining in Part 53, or whether you are using a more traditional process with the PRA in a supporting role?

MR. NICHOL: Yes, that's a great question, and I'll get to this is a little bit more clarity later when I talk about purpose and performance criteria for programs, but essentially yes. If we look at the programs, meaning the administrative controls that the -- I'll just focus on the licensee. I know that they apply to say design certs and that

sort of thing, but if we just focus on the administrative controls of the licensee, the scope of administrative controls that need to be -- that the NRC needs to require for a formal program needs to review and approve and have some change process, change control process in place that ensures that the NRC reviews the changes they need to review -- so within the scope of that broadly it would be the same whether you're using a fundamental PRA approach like LMP TICAP or whether you're using a traditional approach, PRA in a confirmatory role. There will be differences in the details.

So where an LMP TICAP approach the PRA is more important you may have program -- I'll just say you may have some controls within a program that apply more to the PRA whereas a traditional role you may have controls that apply more to the deterministic side of things. So the details underneath might be different between the two, and that can be handled in guidance, but the broad scope of controls would be the same.

MS. VALLIERE: Okay. Thank you.

MR. RECKLEY: Yes, Marc, this is Bill Reckley. Some of what we were trying to do, and I'll

pick criticality safety as an example -- since we were trying to make this technology-inclusive, we were looking to how to do that. So 50.68, obviously a light-water reactor-specific requirement -- and so the notion was this -- by moving it over to a program, a vendor or a group could come up with a generic approach to that.

But it was simply our way of trying to accommodate the fact that there would be a lot of different designs and maybe a lot of different ways to attack that problem. So moving it over to a technical requirement as opposed to a program requirement -- we'll take that under consideration. I mean it was just our way to capture the potential differences between designs.

MR. NICHOL: So --

MR. RECKLEY: Go ahead.

MR. NICHOL: No, no. I was going to reply with a segue into the next slide, so go ahead and finish.

MR. RECKLEY: No, I guess that was it.

The other thing; and you'll see this, you've seen it already in some areas; as we get into staffing you'll probably see it even more so, that the

desire to make technology-inclusive provisions within this part are going to require evaluations to take the place of the prescriptive requirements for light-water reactors and the approaches that have been taken to get exemptions from those.

And so I think some of the responses that I'm hearing is you've got to build in not only that there's a requirement in Part 50 or 52, but from our point of view in requiring some additional assessments or programs it is what would take the place of the prescriptive requirements and lay out a basis that we don't have for some of these technologies?

And so I know that's kind of a broad statement, but the challenge we were facing is this is a universal part for any technology, and so that introduces a lot of uncertainties in terms of things like aging management.

The other thing we were trying to build in from an integrated approach was if aging considerations and monitoring are not taking place from day one, then the designer will have to provide a very high -- potentially higher level of proof that the machine can make it all the way through at least the first term of the license. And so by including

programs -- again we were trying to take an integrated approach where we look at both design, programs and people and considering them together from the beginning.

But we'll take all of this under consideration.

MR. NICHOL: Yes, well, thanks, Bill, because that really helps. It segues into actually what I'll get into two slides from now. So you talked about the Criticality Safety Program, get away from a sort of design requirement and put it into a program somebody can manage.

I think in two slides we'll get to what is a regulatory philosophy around this. And it could be just you have a different regulatory philosophy than we do, and that's important to get straightened out because that could contribute to us talking past each other.

But when I get to the regulatory purpose slide, I don't see an ability to replace a design requirement with a program requirement. I see those as two fundamentally different functions within the regulatory framework that one doesn't substitute for the other. So I think if you all see it as those

being substitutionary, we need to figure out how that works because we don't see that just yet. And I'll go through the slides to explain why we don't see that, because it will be helpful.

But, and then the other one on the Integrity Assessment Program, I do get there may be this consideration where somebody has a feature they're relying on and they don't have a lot of the data, or they don't have a complete set of data to say that it's going to last the entire life of -- let's just say the plant. And so within that you need to have some program to make sure that it's going to last the life of the plant.

We're not arguing against that. Even 50 and 52 have provisions to allow that. I'd even throw in the Reactor vessel Specimen Sample Program might be sort of that vein. And so we're not against that, but what we saw is the -- at least the way that one was written it was doing much more than that. So there could be -- under some of these a fact where the NRC was trying to accomplish something, the way we read it didn't accomplish that. We thought it was doing something else. So there may be details under here we need to work out and that would be helpful as well.

And then the last comment before I go onto the next slide is we -- while we did the evaluation to say well, how does it compare to 50 and 52, we did that because we saw so many programs under Part 53 and we said well, wait a second, why are there so many? How does it compare? We're not suggesting that this is the way on how you develop Part 53 programs. The next slides are going to show how we think you should go about developing Part 53 programs in a more technology-inclusive, performance-based, and risk-informed way. So I wanted to get those point out there, and then if we can go onto the next slide.

So this one is just wrapping up our conclusions of that evaluation I just went through. It comes across at least as an unstructured approach to developing programs. It seems like a hodgepodge. They're just thrown all over the place. We don't see how they're sort of integrated into the thinking or integrated into a regulatory philosophy.

That's going to be -- my comment on the next slide is what we think that should be. And primarily our concern is that the outcome is the expansion of the NRC's regulatory footprint over licensees' controls is dramatically expanded. So this

is a lot more NRC control over programs and also when we get to programmatic information as I get to the rest of this slide.

So that's a concern. We're seeing increased regulatory burden in design and analysis, increased regulatory burden in programs, and we're wondering when are we going to get to an efficient Part 53 as compared to what you would have to do under Part 50 and 52.

So the other concern we have here; I talked about just programs before, we've got another layer that Part 53 introduces and it's called Programmatic Controls. And it's not clear whether programmatic controls is intended to be a program. The way it comes across is that a program is more formal. It would be bigger. It would be more comprehensive. Programmatic controls might be more targeted to a specific requirement. It shows up in about 20 different requirements. And so it may be a couple pages of specific administrative controls that have to be done according to that specific requirement.

But when you look at it, it is in effect mini programs. So there's in effect 20 more mini

programs that you have to add to that list. And one, it's the expansion of control again, but the biggest concern I have with the way programmatic controls are introduced in Part 53 is it's often stated as design features and programmatic controls must be provided for -- and then whatever the for is. For meeting the safety criteria, whatever it is.

The problem is that it's not performance-based. It's not clear, it's not predictable. This uncertainty and subjectivity of it lends the question of well, how much program controls is appropriate? Which programmatic controls do I need to introduce. When do I stop? It really becomes -- it could be resolved in guidance, or clarified in guidance, but it really lends itself to having to be negotiated by each applicant. And we don't think it's necessary to be included at all, but I didn't want to put out there the concerns about how you would actually implement a rule with a pervasive use of programmatic controls.

Let's go onto the next slide for regulatory philosophy. This is going to move us into the ideas that we've developed with our task force on what would be a better approach to looking at programs under Part 53 so that what we end up with is something

that was thought through holistically, not just holistically as programs and administrative controls as whole, but as -- in terms of the question why do we even have programs at all? Why does the NRC even have to require a specific program or why does the NRC even have to review and approve a specific program and other programs they don't have to do that for?

So when we think about it we think you really need to have a regulatory philosophy before you begin this. I apologize for sounding like a broken record. We've been making this comment to the NRC for over a year now that we think you need to have a systematic approach to developing the rule which starts with the fundamentals on what you're trying to achieve. Here the regulatory philosophy is sort of an embodiment of that.

And so this is our effort to put forward a high-level regulatory philosophy for Part 53 to explain where programs fit in so that -- because once you understand why you need a program, why does the NRC have to review and approve the program, then you can have objective criteria to evaluate do we need this program in Part 53? Can we achieve the same thing more efficiently? So that's the whole purpose

of doing this. And we'll get into more details on how the philosophy translated into an actual framework in the later slides.

But the regulatory philosophy in our view needs to start with the Atomic Energy Act, and primarily the Atomic Energy Act is provide reasonable assurance of adequate protection of public health and safety.

So in doing this we think within the regulatory philosophy for Part 53 there's four fundamental features: The first one is you have -- the NRC has to define the standard of adequate protection and it needs to be defined in terms of radiological consequences to the public health. We think you've done this with things like the 25 rem for design-basis events and that sort of -- and normal operations dose criteria, those things. We think you've done that.

The second one is the NRC needs to establish the types of technical features -- I'm going to come back to that term because we picked it for a specific reason -- technical features and the corresponding performance criteria that are necessary and sufficient to satisfy adequate protection

standards. So there's a lot built into that. And a lot of this is what we're discussing with the NRC because that's -- the bulk of the regulations fit within this.

So technical features, we'll come back and we'll talk more. It's design features. So it's the actual SSCs and safety functions and design criteria that you have. There are human actions you have to do. And then there are programs. And they all interrelate which each other and they have their own specific function under the regulatory paradigm, and I'll come back to that.

But most importantly within the requirements they need to specify the performance criteria because otherwise it becomes subjective. So we need to know exactly what performance criteria is acceptable within those features. They need to be what's necessary and sufficient, so necessary meaning that if you don't have -- if you're missing one, then you can satisfy the adequate protection standard, sufficient meaning that you don't want one more than is necessary. If you can do with 10, you use 10; you don't use 11 to meet the adequate protection standard.

So within this these would be a lot of the

requirements the NRC is developing in terms of like I just mentioned the safety features, analysis requirements, that sort of -- so even the operational requirements, those types of things. So there's more work to be done on that, but that's where the bulk of the Part 53 work is being done right now.

The third element of the regulatory philosophy is the -- I'll say it's a licensing basis. What is the type, the scope, and level of detail of that technical information? So the information that's describing the technical features and describing how they've satisfied the adequate protection standard. What amount of that information does the NRC need to review and approve to be able to have a reasonable assurance that those technical features meet the adequate protection standard? So we call this the licensing basis.

A lot of times we focus on the safety analysis report. It is more than just the safety analysis report, but it's the safety analysis report. It doesn't in my opinion include the programs because the programs are being reviewed and approved by the NRC and the NRC has a Change Control Program, or requirements for a Change Control Program so they can

review changes that they, the NRC needs to review. So it includes a lot of those things.

The last piece is also important, and we're going to talk about its importance more later, but it's the scope and level of -- it is NRC oversight and inspection of the licensee. I understand this expands to design certification applicants and things other than the design. We tend to focus on the licensee because they have the full scope of considerations, but that oversight and inspection to provide reasonable assurance of compliance with the license and requirements.

So it's important to emphasize here that a program isn't the only mechanism the NRC has to make sure that the licensee complies with the license and requirements. The oversight and inspection is actually that tool that the NRC has. So this helps to inform well, why do we actually have programs if the oversight and inspection is performing that assurance of compliance? So we'll come back to all those questions in more detail.

The technical features here, I just wanted to illuminate where we think programs fit in. So as I mentioned before, you have design features and human

actions and programs. So really the design features and human actions work together. The design features have to perform a function or perform an action and they're credited in the safety analysis report and -- the credit of that, performing that function or action. It gives the NRC the reasonable assurance that yes, the plant is going to operate in a safe manner.

Similarly you have human actions that are going to need to be taken as well. The goal is that advanced reactors have fewer human actions that current reactors, but nonetheless you'll still have human actions, whether that's operator actions -- you might have security actions, you might have other things that are relied on or credited within the safety analysis to do that.

So then the question is well, where do programs fit in? Well, programs -- the role of programs in our opinion is to provide reasonable assurance that those design features and human actions that we just said have actions described in the licensing basis and the performance of those give reasonable assurance that the design will operate in a safe manner. Well, the program gives the reasonable

assurance that they'll actually take place when they need to take place.

So within that paradigm -- that's why I said earlier I don't see an ability to trade design feature for a program. I can see a design feature being traded for a human action, but if you get rid of the design feature and put it into a program, then that's suggesting the NRC doesn't get a chance to review what that design feature does as part of the holistic design.

And so, and then it's within the program. Well, why do I have a program around something that isn't credited or relied upon in the safety analysis report for performing a function? So that's sort of the inability to make a tradeoff between those two. So in a sense the program is almost like a layer of confidence that the NRC has.

But the other important thing is not all of those programs that are used by a licensee need to be approved by the NRC. As we said before, the NRC already has the oversight and inspection, and actually I'll get to this more I think on the next slide.

If you'd go to the next slide, please? So the NRC imposes requirements and they're effective

after the NRC issues them. So those requirements are never non-applicable to -- once they're instituted into the license. As I mentioned, the NRC has the Oversight and Inspection Program. And the licensee is competent in fulfilling their responsibility to perform administrative controls. Basically, the licensee, because they have to comply with the requirements, they're going to take the actions to comply with those requirements.

So the question is well -- the answer is not that the NRC has no footprint over administrative controls. That is not what I'm saying. But the point is saying that the NRC doesn't have to have a footprint over all licensee administrative controls. So the question now becomes where is that line? Where is enough, enough and where is more is too much?

So the first place to start in our opinion is to recognize that the QA Program does a lot in order -- I should say in terms of making sure those SSCs, those design features and human actions perform when they need to perform according to the licensing basis.

So this middle bullet down here is actually a direct quote from Appendix B. The QA

comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. That's a pretty conclusive statement that the QA Program has all of those things that are needed to provide that confidence.

So the question -- so when you look at that, you have to say well, yes, we should have a lot of confidence in the QA Program. And if we do have a lot of confidence in the QA Program, well then what we need in terms of programs beyond that should be pretty minor and we should have a pretty specific reason on why the QA Program doesn't give us confidence in those specific few areas.

And so we should use that as a real discernment. That should be a pretty high threshold to cross in terms of saying the QA Program doesn't provide me enough confidence. I need another formal program to be required under Part 53. So that's sort of the floor that we start at and then we try to build up to see well, what more do we need? So in terms of programs we know we've got the QA Program. We have to have that. We've got the NRC oversight and inspection. Beyond that what programs do we need, if

any? And so the next slides are intended to provide our response to that specific question.

So just mentioned the first bullet. So how we approached answering that question: what more do you need than the QA Program, we looked at it and said well, we've already defined why you need a program to begin with? And we -- well, we started with what's the regulatory philosophy on -- and why do we have a program? And now we've got to answer the question why do we need more -- where would we need more than a QA Program?

So we look it. And what we did is we divided by stages of the plant: design, manufacturing and construction, maintenance, operations. Four phases. This generally aligns with what the NRC has divided up in terms of the plant stages in Part 53. We thought it was a good way to divide it up.

And within that we define well, what is the overarching goal for a program within that stage? So when we looked at design, why do you need a program and it's to provide reasonable assurance that the plant design is in accordance with the license and regulations? That's the answer we came up with.

Same thing, manufacturing and

construction. Well, it's to provide the reasonable assurance that the plant is constructed and manufactured according to the license and regulation. You'll see that come up quite a bit. Everything has to tie back to the license and regulations, to what the NRC has reviewed and approved. That licensing basis becomes critical.

The maintenance, the goal here is provide reasonable assurance that the SSCs are capable of performing their independent functions described in the SAR. So they're capable of it, meaning that they're available within maintenance, meaning that they haven't degraded to the point where they -- you've let them atrophy in the plant, those sorts of things.

Then operations is provide reasonable assurance that the plant is operated according to the license and regulation. And this is where we'll actually have the most interesting discussion around different programs.

Once we established those purposes or goals for each of those stages, we then said well, let's drill down a little bit more. This is supposed to be a performance-based rule. What are the

performance criteria for each of these programs? So these are pretty high-level statements. Certainly it doesn't provide a lot of clarity on saying well, if I -- take design for example. The design is in accordance with the license and regulations. Well, how am I going to know that I've got the administrative controls or the NRC has I'll say a regulatory footprint over the administrative controls that give the NRC that reasonable assurance?

So we drilled down and developed some performance criteria. We evaluated where programs under Part 50 and 52 would align with those. So you can see exactly that it -- so the purpose of this -- because we didn't go to the next step of saying here are all the Part 53 programs and how you develop them. We wanted this to be an introductory conversation on the whole topic of programs.

But what we did is said well, if -- it should line up with Part 50 and 52 and if it doesn't, then that might suggest Part 50 and 52 has programs they don't need or are missing programs they should have. So let's first just compare it against 50 and 52. Then we'll move onto to talking about how we do it under Part 53. The specific programs I should say.

But within that we also identified historical administrative controls the NRC doesn't have to approve because this helps illuminate that this is where the traditional line has been drawn. I should have prefaced at the beginning this was quite an effort because even under Part 50 and 52 the NRC doesn't define what a program -- why you have a program, what is the purpose of a program in the regulatory environment? So this is sort of creating this that should have existed for a long time. But nonetheless, it's helpful now.

Next slide, please? So now I'm going to walk through the performance criteria and those other two factors that I identified for each of those four areas.

So first, in the design -- so remember reasonable assurance. The design is in accordance with the license and regulations. Well, we have to do four things that we identified: So the regulatory requirements, the design-basis that is in the license approved by NRC translated into specifications, drawings, procedures. So all of the lower-level or further downstream pieces of the design.

The second is the design process itself

has to use appropriate quality standards, select the right materials/parts, has to be suitable for the safety significance, and has to provide for verifying the adequacy of the design.

Third, the performance characteristics of the SSC that are the basis of the design analysis are supported by validation data. So you can't just have a design and say well, it's going to do this and not have the data to back up your claims for how it's going to perform.

And then finally the design changes are subject to the same design control measures and approved by the same organization that originated the design. So that one sort of has continuity of the design throughout the life of the plant.

So if we look at those performance criteria and we look at Part 50, all of those are fulfilled with Criterion III in Appendix B, Design Control. Every single one of those. You don't need anything more than Criterion III to be able to meet all those performance criteria which we think are the only performance criteria you need to -- under the design area.

There are a lot of other programs that an

applicant has that are not required to be approved by the NRC: change control, records updates, FSAR update, Reliability Assurance Program, environmental qualification, all those. Now sometimes some of those programs might be submitted to the NRC for review and approval, but not required as such. They Environmental Qualification Program is somewhat a subset of the QA Program in that context.

So let's move onto the next slide. So within manufacturing and construction the goal here is reasonable assurance, plant is constructed/manufactured in accordance with the license and regulations. This one also has four performance criteria.

That the as-built SSCs are consistent with their as-designed specifications. So the design that is the basis -- that serves as the licensing basis aligns up with the as-built.

That the applicable regulatory requirements are referenced in procurement documents, especially QA requirements, Part 21 requirements, that sort of thing. That they're passed down into the procurement chain.

That the procured -- three, procured

material equipment services conform to the procurement specifications. It's not just enough to pass those down to the supplier; you've got to actually confirm that that supplier provided you what you asked for.

And then four, the as-built SSCs prior to operations are capable of performing the functions described in the license. So this is sort of a test of the functionality of those SSCs to make sure that they can perform the way they're described in the licensing basis.

When we looked at the Part 50 requirements that would meet those performance criteria, it's almost -- most of them are addressed through Appendix B quality assurance requirements again. A couple specifically are laid out here that we think are there.

Again, I mentioned this earlier, augmented quality. It's defined by the applicant. There's no QA requirement that says the minimum standard for augmented quality, but that program is submitted to the NRC for review and approval. And then the initial Startup Testing Program is also important here. So those are the ones that address it.

There are programs that the NRC doesn't

need to approve: non-safety-related, QA, the Procurement Program, the Receipt and Verification Program, the turnover from construction to operations. Even reporting defects doesn't have a -- the program that the licensee implements for Part 21 does not have to be reviewed and approved by the NRC.

That one is I think is a good illustration of where the NRC has felt comfortable in the past of yes, the licensee has controls. We don't have to review them, we don't have to approve them, we don't have to make -- check their changes to their program, but we can come and inspect them. And we have oversight and inspection and we can cite them for Part 21 violations if they don't implement the regulation the way that the NRC has deemed appropriate.

Next slide, please? For maintenance this one is a little bit more simpler. One could make an argument to combine maintenance and operations, but anyway this is that they're capable of performing, that their ability to perform has not been degraded since you began operations.

So the first criteria is SSCs during operations continue to be capable of performing as described in the license. And the second SSCs for

which code or regulations require periodic inspection or testing are confirmed to have not experienced unexpected degradation.

So this is primarily in two areas: the Maintenance Program, ISI/IST, perform those -- or accomplish those performance criteria. We did note that the Material Safety Surveillance Program, Appendix H, if it's applicable, would fit within this maintenance area. That's LWR-specific, so it's not going to be applicable to say a different type of design.

There are programs within maintenance that the NRC doesn't need to approve: the FLEX equipment, maintenance procedure development. There are others that the NRC doesn't have to approve.

Next slide, please. Finally, we get to operations. This is the one with the most programs, the most interesting to discuss. And here again the plan is operated according to the license and regulations. So all those functions that are described to be performed are actually performed when they need to be performed.

So three criteria that we identified here: the plant stays within the licensed conditions of

operations; the administrative controls provide reasonable assurance that human actions credited for protection of public health and safety will be performed when needed; and finally related to that, the humans relied upon are trained and capable of performing assigned actions as described in the license. If you have those three, we think you meet this goal of the reasonable assurance that it will be operated according to the license and regulations.

So when we look at the Part 50 programs that would align with those performance criteria, we find a great many of them: tech specs, training and re-qualification for operators and fuel handlers. There are some other identified positions. That's sort of a combination of a couple, so there's a couple requirements there.

The operating plans, normal and emergency, Fire protection plan, Radiation protection, emergency planning, security, environmental protection. All of those would be Part 50 programs that are needed to meet these. Now keep in mind those programs are required under Part 50 because of the large light-water reactor technologies. It doesn't mean that an advanced reactor necessarily has to have each of these

programs to be able to meet the performance criteria.

For example, if an advanced reactor met the security-by-design requirement, or I'd say the criteria that's being developed in the limited scope rulemaking, then well, maybe they don't need to have a security program that's reviewed and approved by the NRC. They would have their own security program. They would obviously have a program for implementing security at the plant; just wouldn't need to be reviewed and approved by the NRC. You can say that for others depending on the nature of the design.

This sort of leads to what, Bill, you were trying to accomplish in your single change control process for programs, which is well, if you go and define the -- if you define the need for programs and the requirements for programs along these performance criteria, which I think is the right way to do it rather than prescribing all these different programs, define the performance criteria you need and let people figure out how to meet them. And if they need a security program, they have one. If they don't need it, they don't have one.

But if you do it that way, then I think it becomes much simpler and you have a better opportunity

for having a single change control process for programs, much more efficient in terms of making sure the NRC -- the programs that are required by the NRC, that are reviewed and approved by the NRC and for which there are change programs are only those that are focused on safety significance and actually need to be in that category, much more efficient for industry and for the NRC.

I should have mentioned here on the far right the programs not needing approval. There are a lot. Effluent Release Program, Worker Safety Training Programs, OSHA worker safety, procedure development. Event reporting is another one. We don't need the NRC -- or the NRC does not require that they review and approve the Event Reporting Program under these requirements.

So next slide, please? So this will wrap up the conclusions. I'd be interested if the NRC has more feedback after this.

But we did note -- so the NRC asserted a long time ago when we were raising concerns that the design and analysis requirements were -- had more regulatory burden than 50/52 equivalents. The NRC came back and said wait, you haven't seen the programs

area. That's where we're going to save you a lot of regulatory burden. You're going to see it more than made up for that increased regulatory burden in design and analysis. You're going to see more than that it reduced in the regulatory burden of programs.

We think the NRC has actually increased the regulatory burden of programs, design and analysis, as well as the licensing basis, and so we haven't seen where any efficiencies have resulted yet.

The second, and we really think this is what the NRC needs to do, is establish a regulatory philosophy for Part 53. We know we've said that for a year. The NRC hasn't done it. I'm not going to be naive and think the NRC will do it, but I think that that would go a long way into making sure that Part 53 is developed not just holistically, but efficiently. Because if it's not efficient, if it's not more efficient than Part 50 and 52, I don't believe anybody will use it.

So part of this and most important for this discussion is defining why do we -- why are programs needed, specifically NRC reviewed and approved programs? Why are they needed? And having that understanding and drawing that line between these

programs are necessary and are sufficient for the NRC to have to review and approve. And these other areas the NRC doesn't have to review and approve them. We know that there's the QA Program that permeates everything. We know the NRC has oversight and inspection to be able to enforce compliance with requirements. Based on those we've got a lot of confidence, which I think we all should have a lot of confidence in the NRC oversight and inspection as well as the QA Program.

So specifically on the programs' 11 areas I have equivalents. I'm not saying that all 11 areas have to be or should be in Part 53, but I am noting they have equivalents. So at least if the NRC wanted to take the easy route, you could just say well, rather than develop a regulatory philosophy and a purpose for programs let's just default to the programs that we've always had because we know that in the past that's given us the confidence we need. There're 13 programs that don't have an equivalent or duplicate others. We think those are easy to just start to delete, especially the Facility Safety Program.

And then the 20 instances of open-ended

requirements for programmatic controls. That whole concept needs to be rethought. And if there is a need for programmatic controls beyond what programs do, it should be very targeted, should be very few of those, and it should be very specific on how you meet that programmatic controls requirement.

And then finally within the programs, and maybe this is future discussion as we get into the details of how these -- the detailed requirements of each program and how they're formed, but really, they need to be performance-based. They need to be graded because not one size fits all. They should have some entry criteria because maybe they're not applicable in some cases. This is if the NRC goes down the path of having specific named programs.

Even better than that might be just to take our performance criteria that you have and have this idea of administrative controls. You've got a requirement. Here's the administrative controls the NRC needs to review and approve, and it's the ones that meet those performance criteria. And then you could have guidance that explains what controls you have underneath them.

The benefit of that, I sort of liken it to

a single document of administrative controls rather than 12 programs that the licensee has to maintain. If you have that one document that's sort of the program equivalent to the safety analysis report, it's much more efficient. I'm sure at operating plants today those -- all those programs they have there's duplication and overlap among different programs. So being able to do that would be an advantage. But certainly there is the best way to do it, but we're also realistic in knowing there's not a lot of time left. So there's also the easy way to do it.

So with that I appreciate the time and would enjoy having more discussion or answering questions or receiving any feedback on your thoughts.

MR. ANDRUKAT: Awesome. Thank you, Marc.

Bill, I don't know if you or if anyone on the NRC side wants to say anything at this point, but the next thing on the schedule is basically to open up discussions to final comments and questions on the topics presented today, basically opening it up to everyone, which is slide 35, the next slide here.

MS. VALLIERE: Hey, Dennis, perhaps I'll just make a comment. This is Nan Valliere again from NRR.

MR. ANDRUKAT: Sure.

MS. VALLIERE: Marc, I just wanted to note that -- to encourage you to take the presentation you've given us here and maybe consider it when you see the remaining subsections that are coming out, and in particular Subpart H, which is content of applications for the remaining licensing processes, because I don't think we're going to be

-- have the time to give your feedback here today proper turnaround in that rule text. And that may be a place where you can make some concrete suggestions with regard to program areas that are highlighted in those content of application sections.

And then perhaps I can just ask you -- back on -- I think it was slide 26 you have taken issue with this phrase that appears often in Part 53 related to design features and programmatic controls must -- and then, you know, do something. And I wondered if you or your colleagues have given any thought, whether you had in mind a way that we could reword that phrase in Part 53 that would perhaps address your concerns with it, but at the same time still allow us to indicate that it's a combination of both designed elements and promote programmatic

controls that can be used to address requirements.

MR. NICHOL: Yes, I think -- so first, we have provided our detailed thoughts on that question back in our February discussion draft we proposed. The essence of it is that the phrase doesn't actually add anything. So if the requirement -- if it says design features and programmatic control must be provided -- I'm trying to see if I can find real quick an example -- must be provided for each plant to ensure the contribution of total effective dose is less than X. Well, if you just delete the phrase design features and programmatic controls must be provided and you just a requirement that says you have to meet that dose, you're effectively doing the exact same thing, so without adding in uncertainty and lack of clarity and subjectivity to what the sufficiency of design features and programmatic controls would be. And then you could add in somewhere else the concept -- you could add it just one place, the concept that design features and programmatic controls work together.

So certainly there could be place where -- in our draft we had put it together in a framework that we thought was more comprehensive. So you could

always go back and look at those detailed suggestions that we provided back in February, the discussion draft. But you could have it in one place that basically says the combination of design features, programmatic -- human actions and programmatic controls are -- give the adequate -- or the reasonable assurance of that adequacy.

And then you can define programmatic controls somewhere else and specify -- in its own requirement, but specify these are exactly why you need programmatic controls and what they have to be able to achieve the performance criteria. And to have it one place I think would be much simpler and more efficient.

MS. VALLIERE: Okay. Thank you.

MR. ANDRUKAT: Fantastic.

Bill, I don't know if you wanted to add anything before we -- I know we just talked about a lot of stuff just now.

MR. RECKLEY: Just maybe a general caution --

MR. ANDRUKAT: Sure.

MR. RECKLEY: -- of I think what we were trying to do in Part 53. You really can only see it

when you apply it to a design. If you're going to just count regulatory requirements and compare it to Part 50, you probably will not end up in the right place.

QA is -- yes, we acknowledge the importance of QA, but looking at how we thought this would work where there would be less safety-related equipment -- but in order to take a risk management approach more equipment under special treatment, that's a certain result. And it's afforded by being able to say you have QA, but it's going to be limited. At least the full Appendix B-type QA would be dedicated to a smaller set of equipment.

And so just a caution of looking at this in hypothetical versus looking at it for particular designs. Because I continue to think if you look at it for particular advanced reactor designs, it might lead you to a different conclusion than just doing comparison to regulatory text.

And then that also leads into when you put more reliance on non-safety-related equipment to help you manage the overall risk of a plant, while some other programs may come into play because you have less reliance on Appendix B and more reliance on some

of the other programs that would help deliver special treatment. So just a caution of when you're looking at it and doing comparisons. And that's all I have, Dennis.

MR. NICHOL: Yes, Bill, I appreciate that and I can understand how our comparison of 53 and 50/52 comes across that way. I'll say we did that because we can't figure out another way to communicate what -- we can't figure out another way to communicate back the increased burden we're seeing in Part 53 compared to 50 and 52.

We have -- in our mental minds we have applied these to designs, each one to the design they know the best. And what we see is as you apply it to a design, the design and analysis requirements -- if you do it under 53, just take that design under 53, it's more burdensome than 50 and 52. If you take that design and apply the program requirements it's more burdensome than if you apply the Part 50 program requirements. You do it to the design-basis information, you have to submit and control, it's more burdensome than 50 and 52.

And so when we do that, there's several reasons why. We can get into all the details. But

the problem is when we do that, it's difficult for us to come back and say you're adding more burden. And the NRC's response has been well, don't look at the design and analysis burden. You have to look at the whole. Wait until you get the programs and operations, and you'll see there's benefit there.

We wait. We look at those. We see more burden. And then we get well, don't look at that. You have to wait until you see the licensing basis stuff and you're going to see the benefits there. And we look and we wait and we see more burden there.

And so you're a little bit frustrated. It's burden -- it's more burden as a whole than when you apply it to design in Part 53 than 50 and 52. And so we ask ourselves well, how can we convey that to the NRC? And the best we can come up with is well, let's compare it to 50 and 52, show where it's different, and hopefully the NRC will look at that and come back with a reason why you have to have that requirement that 50 and 52 doesn't have.

We do think the NRC has the burden of saying why you have to include requirements in 53 that you wouldn't have in 50 and 52. And we've never -- we haven't gotten from the NRC an -- I'll say an example

of how 53 would be less burden than under 50 and 52 for a particular design when you take it as a whole. So we're sort of left with this rule that's headed in a direction that's more burdensome from 50 and 52. We all want this to work. We all want to be able to use Part 53, but it's really not headed in that direction. And that's our concern.

I'll take an example in the design and analysis. You talked about how the idea is to move things out of safety-related and move them into non-safety-related special treatment. We see that. We see that that's happening. We see that that's happening primarily because of how people use PRA, not because of how the requirements are crafted. And I think you even said that specifically yourself in a previous meeting that it's the use of the PRA that enables all these advantages, not the construction of the requirements.

And so, but within that we also see increased burden. So the special treatment that's being applied to the non-safety-related special treatment, it's almost the same as the special treatment applied to safety-related equipment. The scope of the NRC's control over non-safety-related

equipment for this design that we have in our minds, we see that scope increasing. That primarily is related to design requirements related to ALARA.

So I understand you see a decrease in safety-related components as they move into non-safety-related special treatment. We see it, too, but we see a lot more things being burdened and we don't see that tradeoff. The benefit from moving things out of safety-related is more than offset by the increased burden that you're placing on special treatment and on safety-related things, programs, and other things. That's what we're seeing.

If there's a better way for us to communicate it rather than compare it to 50 and 52, we'll do that. We'll provide it to you. But we can't figure out another way to communicate it at this point.

MR. ANDRUKAT: Okay. So I think at this point maybe what we can do is open it up to the rest of the field here. And this will be I would say not just comments and questions on what NEI just presented here on programs, but for the other topics that Bill Reckley presented earlier today.

So with that I -- so far I see one hand

up. So I will -- Mr. Keller, I'll turn it over to you.

MR. KELLER: Yes, this is Mike Keller with Hybrid Power Technologies. I'd like to read a statement into the public record.

Considering that most of the advanced reactors are passively fail-safe a reasonable expectation is that the proposed CFR should be less cumbersome than the current CFRs, however that is not the case. There is no question that the proposed 10 CFR 53 includes extensive and onerous new requirements not contained in the current CFRs.

In our view there is a very high probability that the excruciatingly prescriptive path the NRC is pursuing will inevitably lead to the demise of advanced reactors in the U.S. The cost to licensees' passively fail-safe designs will be vastly out of proportion relative to the actual risk to the public.

The recent depressing $2 billion cost to license the passively fail-safe NuScale reactor will likely be exceeded by a considerable margin. That level of unwarranted cost will stymie private investment in advanced reactors because the

regulatory-driven financial risk will be needlessly too excessive and that leads directly to utterly non-competitive energy.

As we have repeatedly raised this concern to no avail, the matter is being raised to a higher level. That concludes my remarks. Thank you.

MR. ANDRUKAT: Fantastic. No, we appreciate your comments here. And looking to see -- I do not see any other -- oh, we got one more raised hand. Oh, maybe not. All right.

Other than that, okay. I'm not seeing any raised hands right now. I'm not seeing anything in the chat. And for those folks that are on the phone only, you can feel free to hit *6 to un-mute yourself and say that you have a question.

Okay. Not hearing any at the moment, let's go ahead and continue.

Let's go onto slide 36, please. Okay. Rulemaking schedule. So on this slide it provides an overview of the current Part 53 rulemaking schedule. And as you can see we're still in the first milestone where the staff is performing public outreach, meeting with the ACRS, working on the draft proposed rule package itself.

Right now it's slated for seven months to complete those particular activities before the draft proposed rulemaking package is submitted to the Commission, currently slated May 2022. The staff is still projecting that the Part 53 proposed rule will be published for public comment in October of 2022.

All right. Okay. Let's go onto slide 37, please? Okay. Future public meetings. The staff is planning to host additional topical public meetings. Right, this was the first in that series, on this Part 53 rulemaking. The public meetings will include new and revised preliminary proposed rule language to continue the discussion on the Part 53 regulatory framework. The staff will also continue to post all preliminary proposed rule language and any comment submittals received on -- said language on regulations.gov under this rule's docket ID, which is NRC-2019-0062. All right. So those received prior to the public meeting.

The NRC staff is also continuing to meet with the ACRS via the Future Plant Subcommittee to receive feedback on the Part 53 rulemaking. And as you can see there are -- the next upcoming meetings are scheduled September 23rd and September 24th, and

there are five subparts being planned to be discussed at this next ACRS Subcommittee meeting.

Okay. If we can go to slide 38, please?

MR. NICHOL: Dennis, could I ask one question?

MR. ANDRUKAT: Sure.

MR. NICHOL: I forgot to ask earlier.

MR. ANDRUKAT: Sure.

MR. NICHOL: Thanks. I apologize for this. It goes back to -- I think John Segala said it at the beginning of the meeting and I'm just wondering if I heard it wrong, it was a misstatement or if it's actually the plan.

So within this alternative rule language for traditional uses of PRA I thought I heard, John, you say that this was going to be a Part 50 update. Did you mean to say Part 53, or is the NRC's intent to not allow traditional uses under Part 53, that they would be under a new rulemaking under Part 50?

MR. SEGALA: This is John Segala. I don't believe that I said it was going to be under Part 50, and I don't think the staff -- we're still developing that. So I don't think we've officially decided where it's going to be located.

MR. RECKLEY: This is Bill, John. I'll just weigh in.

It will be part of this same rulemaking. So we are looking and exploring where the best place to put it is, but it wouldn't be a separate Part 50 rulemaking versus the Part 53 rulemaking. This Part 53 rulemaking will by its nature be quite broad and will touch basically every part within the book.

MR. NICHOL: Okay. That's helpful. Let me just give you some input for your consideration. I think it would be best served to do that, to enable traditional approaches to PRA under Part 53. In my evaluation of Part 53 it would only be a handful of changes that would be needed. One would be to not have a PRA requirement that brings in text from guidance that -- you have it at the appropriate level of requirements.

The other would be to address QHOs. There might be a separate pathway for the change control process. But like I say it's probably a handful of differences that need to be treated -- or a handful of places where a traditional approach would need to be treated differently than what Part 53 does now.

And in comparison, I think if you tried to

make Part 50 technology-inclusive, I think you'd have to revise the entire rule. So I would encourage you to try to put it under Part 53 if possible.

MR. RECKLEY: Understood. It is difficult. In either case it's difficult. And within Part 53, bringing in a traditional element and including the identification of postulated initiating events versus the PRA, bringing in the single failure criterion versus reliability criteria, it's probably more complex than you think it might be. The true statement, Marc, is no matter which one, it gets complicated.

MR. ANDRUKAT: All right. Okay. So this will be the last slide that we're going to speak to. And like we said earlier, there are additional background slides beyond this for your information.

So like I said before, I'm filling in for Bob Beall just for the next couple of days. So he is still the lead rulemaking contact, and so you see his contact there on the screen, right? robert.beall@nrc.gov. So if you have -- if you want to reach out, have questions, feel free to send it to him. You also see on the slide there's Bill's email address there, william.reckley@nrc.gov, as well.

So we welcome additional input or suggestions for future topics related to this rulemaking. Again, please feel free to email Bill or Bob on those. Your interest and comments will of course improve our rulemaking effort on this.

We also encourage you to monitor the Part 53 rulemaking docket on the regulations.gov website. Again, that docket ID No. is NRC-2019-0062. So that will have the updates. That will have the important documents related to this rulemaking.

And finally, we're always looking for ways to improve our meetings and your feedback. It is always important to us. So at the end of this meeting please feel free to go to the NRC public meeting web page, click on the recently held public meetings button, look for this particular meeting, and there's a form there at the bottom. Feel free to fill that out with any feedback you would like to provide.

And so with that I don't see anyone else's hand raised. Okay. So I'd like to thank everyone for participating in today's Part 53 meeting and I hope everyone has a good evening. And we are adjourned. Thank you.

(Whereupon, the above-entitled matter went

off the record at 4:14 p.m.)