UNITED STATES OF AMERICA

U.S. NUCLEAR REGULATORY COMMISSION

WORK ORDER 159

MEETING TO DISCUSS THE DRAFT REGULATORY BASIS TO CLARIFY THE REQUIREMENTS OF 10 CFR PART 21

JANUARY 24, 2013

9:00 A.M.

TRANSCRIPT OF PROCEEDINGS

Public Meeting

APPEARANCES

NRC Staff:

Victor Hall
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Paul Prescott
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Sabrina Atack
Quality Assurance Engineer, NMSS

George Tartal, Senior Project Manager
NRO/DARR

Participants:

Tom Loomis
Exelon

Marc Tannenbaum
EPRI

Chris Earls
Director, Safety-Focused Regulation, NEI

Robert Link
AREVA

Janet Schlueter
NEI

Ted Amundson
Southern Company

P R O C E E D I N G S

BUTCH BURTON: Okay. I think we're going to go on and get started. Can everybody hear me okay? Okay, great. Glad to see all of you managed to show up on what turned out to be the first snow day of the season for us. We thought it was going to be tomorrow, but of course, that wasn't going to happen. So, but welcome everybody. Appreciate you coming. My name is Butch Burton. I normally work as chief of the Environmental Projects Branch in the Office of New Reactors, but today I'm going to be serving as your facilitator along with Joan Olmstead from the Office of General Counsel, and we're going to be facilitating the meeting. The purpose of our role is to really help the meeting to flow and to really make it effective and efficient for everyone who's participating. I want to welcome you and let you know that this is going to be a one and a half-day meeting. We're going to be meeting all day today from 9:00 to 5:00, and then half a day tomorrow from 9:00 and we'll finish up hopefully no later than about 1:00. And the purpose of today's meeting is to clarify and take input on the draft regulatory basis that clarifies the requirements for 10 CFR Part 21, Title Reporting of Defects and Noncompliance.

Again, as I mentioned, my name is Butch Burton and I'm going to be co-facilitating with Joan Olmstead. This is a category 3 meeting. For those of you who don't know what that means, that means that this is really a meeting between the NRC and the general public. We really use these category -- the

category 3 meetings to maximize information exchange and to take input from members of the public. So it really is much more wide open than perhaps some of the other meetings that we have between ourselves and individual applicants or licensees.

I think before we get into the meat of the meeting I want to make sure that everybody has first of all signed in. We have sign-in sheets at each of the entrances and hopefully everyone has done that. If not, please make sure that you take the time to do that at some point during the day. One of the things that we want to do for the meeting is we -- I want to make sure everyone understands that we are taking input and feedback on the draft regulatory basis. That is different than taking formal comments that we do as part of a normal rulemaking. The purpose of the regulatory basis is really to establish a baseline of information to help decide whether or not we need to go and actually prepare a rule. If we decide to do that, it's at the proposed rule stage where we'll be taking formal comments. So, I just wanted to make sure that everyone understands what this is and what this is not.

Hopefully everyone's looked at the agenda. It is ambitious. We want to try and get as much done as we can, but given the topic and the broad number of stakeholders involved, we really don't anticipate that we're going to be able to cover everything today. That's one of the reasons why some of the key issues, as we go through the discussions, if we can't finish them up for lack of time, we're going to put them in our parking lot and we'll evaluate those for further discussion later, perhaps tomorrow, and if necessary, at later meetings. The agenda includes several items. We've -- we're going to have several breaks, 15-minute breaks or so, and we're going to take about an hour for lunch. So

hopefully things will move along pretty well.

Okay. I want to do a little bit of logistics and ground rules, particularly for those of you who it may be your first time here. Hopefully everyone's received copies of the agenda, the presentation slides, and the feedback form. If you haven't signed in, do so at the entrances, as I mentioned. For those of you who may be on the phone, if you need -- if you haven't signed in, we'd like you to contact Mr. George Tartal. His contact information is in the meeting announcement, just to make sure that we have your contact information and we can get you what you need.

We did have a few hard copies of the presentation slides, but that was limited in number. So, a number of you may not have gotten the hard copies that were here. Our hope, in order to save some trees, our hope is that most people would bring copies of the meeting slides themselves, so hopefully you did that.

Okay. Next thing I wanted to cover was for -- primarily for those of you who are calling in remotely, how you can get access to some of the meeting materials. The slides are located in our ADAMS document -- our ADAMS document system. The accession number to get a copy of the slides you would need to put in ML13018A, as in Adam, 272. So, if you can get into our ADAMS system, put in that accession number, you'll be able to get a copy of the slides. If you'd like a copy of the actual REG basis document, again, you can find that in the ADAMS system. That accession number is ML12248A, as in Adam, 200. For those who are -- want to view the meeting via the webcast, what you need to do is to type in http://video.nrc.gov, and that is in the meeting notice if you have a copy of that. Also, if you want to get on the teleconference bridge, that number is

1-800-857-4853, and then use pass code 65957.

Now, the meeting is being transcribed, so it's important that we get a clean transcript, and that's going to require cooperation both from folks here in the room, as well as folks remotely. First thing, if you have anything that buzzes, beeps, talks back, alarms, if you could turn it off or mute it that would be great. Same for folks on the phone. Unless you're speaking we'd like to have your phones muted because we do pick up background noise.

Restrooms. If you go out this door, they are just to your left. Men's room and ladies' rooms are on opposite sides of the hall, if they're both over there. Should we need to evacuate or leave the room, just please follow the directions of the security personnel and they'll muster us together and we'll make sure that everyone is accounted for. When speaking, please use the mic. What we have today is we have one podium mic over here to my left. We would actually prefer if you want to speak that you use the podium mic; however, if you prefer to stay in your seat, Joan and I both have the handheld's and we're more than willing to bring it out to you. So, and when you do speak if, again, for the transcriber, if you would give your name and your affiliation so they can have that on the record.

Last thing, we're always looking to improve our meetings and how we conduct them. So one of the things that we want to make sure that we do is to have you fill out one of our meeting feedback forms, and again, if they're not already there we'll have them on -- at the entrance, each entrance. You can fill them out now and leave them with us or you can take them with you, think about it a little bit, and send it in. The postage is free. For those of you on the phone who may not be able to get a meeting feedback form, you can give me a call and

I'll make sure that you get one. My contact -- my phone number is 1-301-415-6332. Again, my name is Butch Burton. Questions on any of the logistics? The agenda? Okay, great.

Okay. For those of you who may have been to some of the earlier public meetings, I know one of the things that we try to do is to give everybody in attendance an opportunity to introduce themselves, but as you can see with so many people here and there may be -- I'm hearing there are even more -- possibly more people on the phone, I think it's going to be pretty inefficient to do that, so that's why we're asking -- introduce yourselves and your affiliation only if you come up to speak.

All right. So, I think we're ready to get started. First, we're going to do introductions of folks at the table. I am going to be introducing the NRC staff here, and then later on Mr. Chris Earls will introduce some of the industry people. So, let me start.

First, we have Mr. Vic Hall. Vic is a lead vendor inspector with the Quality Assurance Branch in NRO's Division of Construction, Inspection, and Operational Programs, otherwise known as DCIP. Vic will be leading most of today's discussion.

Next we have Mr. George Tartal. George is a senior project manager in the policy branch within NRO's Division of Advanced Reactors and Rulemaking. George will be leading any rulemaking efforts on Part 21 that we'll -- once that's decided.

Next we have Mr. Paul Prescott, a senior reactor operations engineer in the Quality Assurance Branch. He's trained almost all of our vendor inspectors and brings many years of experience to the table.

Next we have Ms. Sabrina Atack, a quality -- attack, I'm sorry. A-tack. Got to get the syllables right. The syllables, right? Quality assurance engineer in the Programmatic Oversight and Regional Support Branch within NRC's Office of Nuclear Material Safety and Safeguards, Division of Fuel Cycle Safety and Safeguards. Sabrina will be leading all the discussions that pertain to nuclear material stakeholders.

And then last but not least I wanted to introduce Ms. Aixa Belen. She's also a reactor operations engineer in the Quality Assurance Branch, and she has graciously volunteered to handle the computer work for us. Okay. So with that I am going to turn it over to Vic for opening remarks.

VICTOR HALL: Thanks, Butch. Thanks, Butch. Oh, it's on now. Welcome everyone. I'm thrilled to see a packed room. I think we've got a good attendance here, much more than a lot of commission meetings I've seen, so I'm happy to see that. A quick word about the process, and Butch touched on this, today's goal is to talk about the Draft Regulatory Basis. This is really an early step in the rulemaking process, and when we're done with the technical work that we do with this document, we'll hand it to George and he's going to run with the rulemaking, the guts of what goes on. The most important word in this document is draft. It's a Draft Regulatory Basis, and that's because we want to hear your feedback. So the goal for today, I will be happy if I leave this room today and I get your critical feedback, your criticism of these documents, and critical is the key word. I want to hear where we've fallen short, where we may have maybe misspoken, where we could do better. We're looking for your feedback, and I promise you there will be no hurt feelings and just in case, I brought some Kleenex.

[laughter]

JANET SCHLUETER: Excellent. You might need them on that side of the table.

[laughter]

SABRINA ATACK: Yeah, we might.

VICTOR HALL: So the plan for today is go through -- we've got 23 technical topics and four administrative changes. It's a big, big agenda. If you divide out the time that we have by the number of topics, you're looking at maybe 15, 20 minutes per topic. I'm sure there will be some really good discussion today on some of the topics, and that's where we're going to take our sticky topics, difficult topics, put them in a parking lot. If we can cover them tomorrow, great. If not we'll form an agenda for future meetings, but the idea is let's identify our difficult areas, get your critical feedback.

And really, I'm going to be as quiet as possible today. I'm going to be in listening mode and writing mode, because I want to hear industry feedback. I want to hear stakeholder feedback. And so with that I'm going to shut up and I'm going to introduce really the star of the show, our industry rep across the table, Chris Earls, and you can introduce the folks that you've --

CHRIS EARLS: Thank you, Vic. I appreciate it, and I want to thank you all for allowing us the opportunity to meet with you to discuss the Draft Regulatory Basis. We really appreciate any time we have -- this sort of interaction. I think it makes the end product much better. What I'd like to do is introduce the folks that are up at the table with me. As with you folks, we've got them designated for certain areas to take the lead in the discussion, and as we go through that'll be apparent. So I'll start with Marc Tannenbaum. Marc is with

EPRI, and he is going to be leading the discussion from our side on the commercial grade dedication area. As you know, you know, EPRI has had and continues to revise guidance in this area and he'll give us an update on where that is and where we see that going.

Next to Marc we have Tom Loomis. Tom is with Exelon. He'll be representing the power reactor communities. He'll be leading the discussion in the evaluating and reporting chapter topics.

On my left I have Bob Link. Bob is with AREVA. He will be representing the fuel cycle community and, again, he'll be jumping in on most of the topics to give the perspective from that community, and I'll skip Janet for a second.

Ted Amundson. He's going to be helping us with the 55-Echo [spelled phonetically] discussion and give us the perspective. Ted is representing Southern today.

And then finally we have Janet Schlueter. She is with NEI, and I want to hand it off to her to describe who she's representing, because it's quite a cast and I'll get it wrong if I try it. Janet?

JANET SCHLUETER: Well, good morning, and as Chris said, thank you very much for the early opportunity to participate in what might be a rulemaking process. It is a good first step. You'll see, I think, that we have a lot of input that we are looking forward to provide, and as you mentioned, Vic, I think that we're looking forward to some subsequent discussions to get through all of the topics. We can't possibly get through those today. It's a complex area, as you know, and at the table obviously we have representatives from the commercial power reactors and the fuel cycle facilities, but for the record, I did

want to make mention that there are many other communities which are impacted, as you know, by the 10 CFR parts that are not at the table, which need to be addressed and need to be communicated with to what degree FSME and NMSS are doing that. They may already be well underway, not necessarily too visible to us here today, but when it comes to industrial users, medical users, transporters of materials, spent fuel, independent spent fuel storage installations, you know, we could go on and on, many other categories under the 10 CFR parts that are impacted by Part 21.

In addition, it's unclear, mainly because it wasn't addressed in the REG basis and mainly just because of the history I believe that's been in place on Part 21, what the role is, if any, of the agreement states in this rulemaking. There are 37 of them, as you know, and they regulate over 85 percent of the byproduct materials users in the country. So, whether or not there are adequacy and compatibility issues, such as with agreement states, is something obviously that you, as the regulator, will need to address and we'll be interested to see how that pans out.

So, again, we look forward to the future meetings. I think at some point we'll need to have a clear indication discussion about to what degree you expect written comments from the industry at this point. I realize it's not the rulemaking process so it's not a formal comment process time, but we're on the record, I guess, today in some way, and then we'll need to figure out whether or not you're actually looking for us to put something in writing to summarize our concerns or comments with the different topic areas in the REG basis. And I'll apologize in advance for departing this afternoon for another commitment. Thank you.

CHRIS EARLS: Thank you, Janet. I'd like to make a couple of comments before I hand it back to you, Vic, just general in nature. As you know, we've had a wide variety of folks review the document, but frankly, we really haven't gotten into a great level of detail; so the feedback you're going to receive today is going to be a little bit higher level than maybe you'd like to get ultimately, but as Janet mentions, we anticipate that there will be some follow-on meetings, at which point we'll get into even more lower level of detail.

You know, one of the themes that you'll hear today in our comments, and I think it's consistent with the feedback we've given you before, is for most of these areas we think guidance can probably address it, you know, and, you know, obviously adjustments to the regulatory language can be made, but for most of the issues we see success paths through a guidance approach and, in fact, in areas such as the commercial grade dedication area, that guidance, development and revision, is well underway and, in fact, we would anticipate that that's going to be completed and hopefully endorsed well before any rulemaking effort could be completed. So, that'll be a general theme that you're going to hear today, is that, you know, guidance is where we think we should be putting our efforts at at this point, and our speakers will go into a little more detail of that as we go through.

One of the things -- questions I'd like to ask you that you may or may not be able to answer today, but as you know, there has been a lot of discussions recently in the industry and with the staff regarding the cumulative effects of regulation, so I would be interested to get feedback to see if the staff has looked at this rulemaking or anticipates looking at this rulemaking in that light, and you know, if you have looked at it, where did the relative priority fall out

given all the other regulatory activities that are ongoing? That's one of the things I've been asked by my management to assess, and so I'd be very interested to hear where you all fall out on that.

Just to reinforce something Vic and I talked about earlier, we noticed that there was a number of variants where you've put in marked up regulatory language in there. We recognize that that was done to kind of give us a better feel of where you're thinking, what you're thinking, but we also recognize that that's not proposed rule language, that's simply just for discussion. So we've not made a real attempt to try to nit-pick or, you know, wordsmith that regulatory language, nor do we anticipate doing that. What I've asked the folks to do for each area is first assess the option, the preference that you've expressed in the document for each area, can't -- do we agree with that? Yes or no. If not, you know, why not? And what are some of the areas that we think further discussion would be good for it? So you should hear that as we go through each of the areas.

And what we're hoping, as Janet -- mentioned again, is that as we get through this list of items we're hopefully going to be able to take some of them off the list, and taking them off the list meaning we're in full agreement and really don't need to have a lot more discussion on it, and then we'll end up with some subset of areas where further discussion probably would be beneficial, and when we look at that then, I think there may be -- it may be more efficient for us to maybe break some of those into subgroups for specific meetings, i.e., you know, maybe we have a meeting specifically on commercial grade dedication topics as opposed to trying to deal with all of the topics at one meeting. That allows us to focus our resources better probably, focus your resources better,

and I think that will be a more efficient way of knocking these things out in the future. So I would hope at the end of the meeting we'll be able to kind of talk through that and see where we're at. That concludes my remarks and so I'll hand it back to you, Vic.

VICTOR HALL: Thanks, Chris. And just a quick word on process on what may be our -- really our immediate next step is based on the feedback today. I don't see why we can't revise this Draft Regulatory Basis, maybe get closer in alignment so that our next meeting, or maybe two meetings from now, we'll be discussing a document we agree more on, so with those areas we agree that check, check, check we can go through and smooth it through. So again, that was the philosophy behind the Draft Regulatory Basis, is get feedback so we can mold this before going through formal comments. So, when we get to the point of written comments we'll try to do that.

I did want to respond real quickly to Janet's comment about our -- the other stakeholders, including the FSME offices, ISFSI agreement states. We did, early in our process, invite a lot of our folks. We looked at who would be impacted the most and who would be impacted. Our initial thought was it's minimal impact on them, but I think this is an area we certainly need to look at more and we'll take back to our office directors and I think we need to get addressed in this document somehow. So there'll be some more discussion, I'm sure, in that area.

The quick word on proposed rule language -- absolutely, thanks, Chris, for pointing that out -- we put the language in there really as -- to give folks a comfort level, because the first reaction to rulemaking is oh my gosh, it's rulemaking. But hopefully when people see what we're talking about in

rulemaking to tweak, maybe a tweak, and say “Oh, yeah, it makes sense. That's a good fix.” So, that's why a lot of the proposed -- or a lot of the language is in there as a guide to what we're thinking. It's not proposed rule language yet.

So with, that let's dig in. I'm going to lean on Butch here pretty heavily, so what we'll do is I'll give an introduction to each topic. I'll ask for the folks sitting across from us for their comments, and then we'll open it up, because I don't want to just keep this a closed meeting. So we'll have folks in the room have a chance, if you want to come up to the mic, or we have mics roaming around, to speak, and then if we have time we'll do folks on the phone and get everyone involved. Please, yeah.

SABRINA ATACK: Just to add on to Vic's comments in response to Janet's remarks, I do want to add that NMSS has been reaching out to stakeholders beyond the Part 70 community, so that's been in process. We've sent emails. We've worked with the NEI contact to make sure we're reaching out to as much of the demographic as we can. If you're aware of anyone we've missed, we're always welcome to receive that feedback so that we can make sure we make them aware of anything that's going on with the rulemaking, and also, as Vic has put a plug in historical meetings, as the Part 21 webpage that has the “subscribe to updates” link, so anybody who doesn't feel like they are aware of all the rulemaking activities and would like to be, you're always welcome to go to that webpage and subscribe to updates and then you'll get emails whenever there's an activity that's coming up.

In terms of the agreement state applicability of Part 21, the OGC has determined that agreement states are not within the scope of the Energy Re-Organization Act, Section 206, so those agreement state licensees are not

required to submit reports under Part 21. I will note that some do so voluntarily, but at this time, based on OGC interpretations, they are not subject to the requirements of Part 21.

VICTOR HALL: Anybody else? Janet, you want to -- or if -- George, I didn't get a chance to -- if you want to say anything -- or Paul.

PAUL PRESCOTT: No. I'm good.

VICTOR HALL: Let's dig in. Real quick, again, we're focusing on the chapters two, three, and four. This is just the table of contents of the Draft Regulatory Basis, so let's go for the next slide, Aixa, please, and we'll go to evaluating and reporting. Perfect.

All right. So our first area for improvement is the lack of regulatory guidance, and if I had to sum it up in a word it's that in 34 years of Part 21's existence, the NRC has never put out a reg guide, which I think we've seen has been a problem throughout the industry. So our first area is to say we need guidance. We need NRC regulatory guidance that explains what is an appropriate evaluating and reporting process that we see as a proper process, and that's the driving force behind this chapter. I'll offer it for comments.

TOM LOOMIS: Yeah, let me pick it up from there.

FEMALE SPEAKER: He's not on.

TOM LOOMIS: Got me now? Okay. Yeah, just to continue on here with what Chris had to say here, again you'll hear that constant theme throughout the discussion, you know, that we're going to be leaning more towards the guidance aspect here, and we also want to make sure we don't lose some of the prior guidance, like NUREG 0302, which has supported us along the way. So we want to make sure we wrap those types of -- we'll call them previous

guidance documents into the system here. So I don't want to lose those.

One of the areas -- two of the areas, actually, we're most concerned about is a), in yesterday's pre-discussions that we had as a group, we realized that, you know, we have the Part 50 people, people like myself, and then we have all of the non-Part 50 trying to craft language that adapts to those people, as well as to our people. It's going to be incredibly difficult, so again, customized language through guidance for each one of these different groups is the better way of going. We've worked with Part 21 for years. Going with, you know, common rule change, we don't see that as being a success path, so good guidance documents are what we're looking for. And also avoiding unintended regulatory consequences from rule changes. That's something that concerns a lot of people, so when people put together rule language, they put it out there, everybody approves it, we all sit around the table and say “Oh yeah, this is great we understand it.” Six months later somebody is going to pick up that rule and say “Wait a second, that's -- you know, I don't read it that way,” and then you're into a lot of confusion. So again, guidance is the way to go. If we need to make changes or tweak it further on down the line we can do that. So two areas of concern.

We have a lot of participants here today. We'll hear from them, as well as we want to avoid unintended consequences through rulemaking, so I'm just going to leave it with that as our comments on one.

VICTOR HALL: Thanks, Tom. And real quick, just a thought, I think we're aligned when we're talking about customized language, and we've -- we have draft guides, which are placeholders right now. When we finalize this document is when we'll start writing these reg guides. And, of course, they will

be open for public comment, so it's going to be a long and tough process, which will keep me well employed for some time, but yeah, that's exactly what we had in mind was customized, you know, for the -- it's just too difficult, I think, just to split out what evaluating and reporting process is going to look like for an appendix B entity versus non-appendix B. So I get it completely. For agreeing on unintended consequences my quick thought was this is rulemaking. It's slow on purpose and the whole idea of the process is slow and painful so that we do make sure we avoid unintended consequences to gather comments from folks. So I appreciate that feedback. It's very good. Do we have any folks in the room that wanted to chime in? Any show of hands or come up to the mic. We welcome your comments.

ROBERT LINK: I guess I'll add just a comment. I agree with Tom. In our pre-meeting, we very quickly got to the point where, no disrespect to my customer in Part 50 land, but their nomenclature, their process, their appendix B commitments, what have you, do put us in a different, I guess, point of view and frame of reference, even in the slide, and I know there are references in here to the criterion in 04 of appendix B. I understand the underlying intent. I'm not disagreeing with that, but obviously many of us are committed to appendix B. We have a variety of approaches relative to quality assurance, graded approach allowed under the rules and regulations. So the guidance absolutely is appropriate and necessary. We're not disputing that at all. Whether or not we want, you know, separate guidance documents, that's more for efficiency and ease of use, so to speak, but at least maybe subsections within a guidance document that provides clarity or even nomenclature that's more conducive to the different entities. I mean, as I stated, I try to represent the fuel cycle facilities, but

even that's very difficult for me to do. We have Part 70. You have different categories under Part 70. You have Part 40, Part 76. We all live in the slightly, but noticeably different, frame of reference, and that comes with some challenges for all of us.

VICTOR HALL: That will be the challenge of our days, is getting the different twists for every different entity.

ROBERT LINK: One additional comment to Tom's relative to unintended consequences, and I know we'll get into this in a little bit more detail in the later sections, but -- and I know we skipped over the introduction, but there's a comment in the introduction --

VICTOR HALL: Sure.

ROBERT LINK: -- where on page four it states the staff did not consider risk informing the part or substantially changing the scope of Part 21.

VICTOR HALL: Right.

ROBERT LINK: Right now I would say that the fuel cycle facilities, even with the information provided in the reg basis do consider this a noteworthy change in scope for Part 21 as it applies to us.

VICTOR HALL: Okay. Any folks in the room that would like to chime in? This is an easy one, so this is [laughs]. All right. Do you want to try folks on the phone?

BUTCH BURTON: Yeah, before we move ahead we always want to --

VICTOR HALL: Butch, I don't think you're on.

BUTCH BURTON: Okay. There we got it. We always want to give opportunity for folks on the phone if they have any comments on any of the topic

areas. So, anyone on the phone wish to speak?

FEMALE SPEAKER: I only wanted to ask if everyone on the phone would please mute their phones, please.

BUTCH BURTON: Okay, yeah. Let me repeat that. For folks who aren't speaking, if you could mute your phones, and for those who are going to speak if you could give your name and your affiliation. Okay, sorry, go ahead.

SID BERNSEN: Sid Bernsen with Anatech Corporation. Please repeat the ADAMS accession number for the slides.

BUTCH BURTON: Oh, sure. Give me one second here. I put that away. If you're interested in getting the slides you get on ADAMS and put in accession number ML13018A, as in apple, 272. Got that?

SID BERNSEN: Thank you.

BUTCH BURTON: Sure, sure. Okay. Again, anyone on the phone who wanted to speak to this initial topic? Okay, hearing nothing, I guess we can proceed.

PAUL PRESCOTT: Yeah, I just wanted to add one thing about that on evaluation and reporting, we've had previous discussions, and I know Chris is aware of it, Tom, Debbie -- I see Debbie today, and you know, I've taken that feedback, looked at it. Obviously my goal is -- I think it's sort of in line with where you're going with it, maybe with a possible tweak to the language, I think, because we tripped over that evaluating and reporting piece in wording, and so, we may add a minor correction to it, but obviously, you know, I heard you in your preliminary meetings that we had and my goal is really to update the guidance. You know, we haven't been anywhere with that document since 1977, you know, granted there hasn't been much rulemaking, except for in '91 when they did the

duplicate reporting and addressed that issue. And so -- but over time, you know, we've improved our processes with the reg assurance and our interface with you people and I certainly, you know, took that to heart and plan on taking that and incorporating that when I consider the guidance, but I do plan to update the guidance.

VICTOR HALL: All right. One is the softball. Let's go on to some fastballs here. Let's go to number two. Next slide please, thanks. Quality requirements and procurement documents. Again, the quick -- I'm going to give a quick overview what I view it says and the spiel is it's not seeing the adequate quality requirements invoked. When something is safety-related, if Part 21 may be invoked or appendix B may be invoked, but I've seen them -- we've seen them done separately, and that's unacceptable, because if it's safety-related it's a basic component, then appendix B and Part 21 apply, at least for Part 50 facilities. So, the philosophy behind this chapter is to modify Part 21 to make it crystal clear that when you are buying a safety-related component you are buying a basic component, you are buying something that has to have appropriate quality requirements for reactor facilities at the appendix B. For non-reactor facilities it's going to be a different set, but making it crystal clear that quality requirements are an integral part of buying something safety-related.

TOM LOOMIS: I would think we would agree with that, that we want to make sure that when a purchaser puts out a purchase spec and they list what their quality requirements are that they're clear about that. But I think one of the things you get into here is -- look, let's take the classic example. The proposed language you have is appropriate quality requirements. That confused us, because appropriate quality requirements could mean just about anything to

anybody. So when you use that type of broad language it just -- it's going to create just a ton of problems for us, you know, appropriate quality requirements, and maybe the best path on this might be just with guidance documents, have a better path towards educating people, like making sure that, you know, your documents specify clearly that it's safety-related. I don't think that's really that big of an issue to make sure that people do that, but putting appropriate quality requirements with inside the regulation just becomes too vague. It means too many things to too many different vendors, especially when you're dealing with fuel cycle people and everywhere along the line. In a classic example here of unintended consequences, and I know this is just sort of language you put out there for us to look at, but when -- I looked at the draft language and you have the one statement on page 11 where you say "on or after January 6, 1978, appropriate quality requirements" blah, blah, blah, “shall apply.” What that -- you know, if somebody emailed me back and said you know, when I look at that, that means that every document that I've issued since 1978 has to be revised to show appropriate quality requirements. I don't think that's what we intended here, but when you look at the literal reading of that language, that's one of the unintended consequences of something like this. So if you put that in there and you say everything after 1978 has to have -- has to be revised for appropriate quality requirements. Once we define what appropriate quality requirements is we're going to have to revise everything. I'm just not quite sure that's where you want to go on something like this. Is the issue the fact that the purchase specs aren't being detailed enough? Or are people not putting the right information in those purchase specs?

VICTOR HALL: I view the issue more as being it's not clear when a

purchaser is buying a safety-related component to the vendor that they are providing a safety-related basic component. It's almost the -- it's not hitting them. Number one, it's in the nuclear industry. It's pretty darn important. So, yeah, I'm meeting appendix B or yeah, I'm meeting NQA-1 because it's in the purchase requirement, but it's not clear because it's -- because well if it's in the purchase order that this is a basic component in that Part 21, in the reactor world, the appendix would be applied. So if I go back to '78 everything from them should've had Part 21 and appendix B in the contract. So, if we define appropriate quality requirements as appendix B, you're not talking about a change. They should've done that anyway. It should've been in there from the start, from 1978. So, the thought of appropriate quality requirements, it's a broad language. I think we can do a better job, but the thought was let's make it clear what's already required, that appendix B should be in these purchase orders for safety-related -- another option could -- just brainstorming. Another option could be to define what safety-related is, and say well, I'm buying a safety-related component it's got to be in the purchase order. You have to buy a safety-related component in here and what comes with that. I don't think it's a clean fix, so someone could take that for appropriate bring broad, but that's the thought behind it.

TOM LOOMIS: I understand what you're saying, yeah, and again, I think maybe we could educate better on that one, and a good guidance document, which talks about this is what the purchase spec should look like. I mean, quite frankly I think a lot of utilities at times are in there struggling, what's safety-related, what's not safety-related? So if you go to a, let's call it an international vendor or something like that, you know they're going to look at this -- and so, you know, we could comply with the regulation and we could tell

someone manufacturing a component in France it's safety-related and it's like, okay, great, you know, thank you. With that said, I'm going to turn it over here to Bob. I think Bob has some input on this as well.

ROBERT LINK: Well, again, and I'll have to probably belabor this a bit. I'd be very careful with equating the word “safety-related” into basic component. In the context of a Part 70 facility, safety-related really is yet to be clearly determined. And I think that is a critical cornerstone issue that we will have to wrestle with, but at least from the verbiage here, again, I can't stress, you know, the rule talks about basic components, so let's stick with what the rule states. Safety-related just fogs the ground for us.

Again, your references to appendix B, I respect them, I understand them, but they really have no relationship to us. So it doesn't add clarity. It actually reduces clarity for us. The -- one of the issues, you know, that we will wrestle with is we'll order -- unless just say I order a pump or a valve, and I will order that valve to its specification, but where I use that valve may determine whether it is a basic component or not. The vendor has no understanding of that. We will write a specification that considers critical characteristics to assure that happens. So somehow we're going to have to wrestle with that dynamic in the marketplace that we're dealing with every day.

But again, it gets back to, at least for us, the nexus is what is a basic component? Is it clear? Is it clearly defined? We completely agree that the guidance is necessary. We're not sure that any rule change is necessary or appropriate, to be honest with you, but clearly guidance is necessary.

VICTOR HALL: And Bob, you scare me, because I'm coming from the Part 50 side, and in the Part 50 side safety-related is, it's the same definition

as basic component. So it's a lot cleaner, a lot easier for the Part 50 side. Now at least from the inspector side, that hook in 21.31 that says, you know, thou shalt invoke Part 21 safety-related and basic component procurement order is what drove saying we should be adding the quality assurance requirements, making clear the nexus between appendix B and Part 21, but the non-reactor side is the piece, I think, is certainly the challenge in this area and something we --

TOM LOOMIS: Was it the fact that you found specs in your inspection that just weren't clear? I mean, is that where this issue is coming from?

VICTOR HALL: It's the issue of asking the vendor point blank: Here's an order that you supplied to X utility. Was this safety-related? Because it's a basic component, and it's not having the clear answer of yes. It's not recognizing that I'm providing something that has to be designed and manufactured under appendix B program, that I've got to put my quality requirements on this component.

TOM LOOMIS: Would that vendor have understood what safety-related meant?

VICTOR HALL: I would hope so if they were audited by the utility.

TOM LOOMIS: Okay. All right. We're talking different vendors here, so that's why I wanted to ask that question.

VICTOR HALL: These are audited vendors who recognize that they are providing nuclear parts and services, but when it comes down to the discrete parts they're supplying, I'm not sure. I'm not sure if this one was, and that's a scary thing to me. It's should be crystal clear when something is safety-

related, and that's the idea, and safety-related meaning appendix B to me. The other piece, not as easy to fix.

TOM LOOMIS: Yeah, let me bring in Eric Weiner -- it's international procurement -- a couple of perspectives from him. I think it's important to hear.

ERIC WEINER: Hi. My name is Eric Weiner. I'm with AREVA Enrichment Services. The one point I wanted to bring up that we've having difficulty with in the enrichment world and Part 70 is the difference between invoking Part 21 and applicability of Part 21 to a basic component. As you know, a new construction plant for enrichment in the U.S., majority of our components are coming from overseas, and we're not typically dealing with your ASME supplier that knows what Part 21 is, we're dealing with suppliers that have no clue about NQA-1, ASME, appendix B, and Part 21. We're looking for alternative methods of dealing with foreign suppliers where we can still buy a basic component because they have quality programs that meet the requirements of our quality program. So the invoking of Part 21 or not invoking of Part 21 is really irrelevant to the overall quality of the product that they're going to supply us as it applies to applying an acceptable quality program. So, we're looking for alternatives. Right now I think there's things out there like in -- for foreign suppliers you don't have to post Part 21, because it's really an American law that is irrelevant over in Europe; so we're looking for a guidance or either alternative methods of applying Part 21 to the order where the purchaser will assume some -- the responsibility of reporting and we'll define requirements for reporting of noncompliance and defects in our contract with the supplier by saying that Part 21 is applicable to the order. So, that's one of the issues that we're dealing with.

SABRINA ATACK: Could I ask what mechanism you have in place

if you're not invoking Part 21 on the suppliers to ensure that you're notified of defects in the products you're procuring?

ERIC WEINER: What we do is we have a couple of thoughts in mind. First, we haven't done much procurement, so there's not a lot of issues to deal with right now for us, and other enrichment facilities that are being constructed in the U.S. have different commitments than us. Our quality program as submitted and approved by the NRC has no commitment to NQA-1 or appendix B, where other enrichment facilities do. So, their linkage is more defined and more appropriate whereas in our linkage what we would propose to do is to provide, with the procurement document, a process or procedure under which the vendor would be contractually obligated to report noncompliance and defects to us for the life of the product rather than say -- and we'll see. Part 21 is applicable, but we, as the purchaser, will assume all responsibility for reporting to the NRC, and I think that's -- really the only difference is you're looking for direct report from European suppliers, and there's no posting requirements for European suppliers, so therefore they really don't have that level of detail to be able to contact you directly if they chose to do so. So, we're just looking for some guidance in this area.

VICTOR HALL: I'm not sure I'd agree with the statement that they don't have posting requirements. If they want to supply a basic component they have to meet Part 21. Now, the legal applicability of Part 21 overseas I'm not going to get into, but it's -- you put it in the contract, they're going to have to meet it.

ERIC WEINER: I understand, but the application of it is you post a Part 21 over in France or in Germany or wherever, the majority of the workers in

the shop can't even read the document, so there's difficulties in applying this rule and dealing with European facilities.

VICTOR HALL: Right. Well, I guess my point would be I would still expect, regardless of where a vendor is, if they're supplying a basic component that they would have to meet Part 21. Absent that you have to dedicate, so if you don't want your international vendor to meet Part 21 then it'll be your responsibility to dedicate it, and that's the only way. You either buy a basic component when Part 21 applies, or you dedicate. There's no other way.

ERIC WEINER: I understand that and that's what we're looking for additional guidance on being able to work through that.

SABRINA ATACK: And is the scope of your problem limited to international suppliers? Or are you anticipating the same issue domestically for basic components?

ERIC WEINER: Domestically less -- much less so, more international.

SABRINA ATACK: Okay.

ERIC WEINER: But understand that's where the majority of our components come from.

SABRINA ATACK: Okay. And can you help me understand a little more what the concern is with imposing Part 21 on those international suppliers with the understanding that if they're not capable of performing the evaluation they are able to notify you so that you as the procuring entity can do it.

ERIC WEINER: Right. For the most part the supplier doesn't have the ability to do an in-depth evaluation to determine the overall impact of Part 21 on a product they've sold. So 99.9 percent of the time they're going to report to

us directly anyways, and then we would conduct the evaluation as to whether or not it's a Part 21 reportable item. By invoking it upon them we are now -- if you're telling me -- what you're telling me is true, is that we now have to have them have a procedure, they have to post in their facilities, they have to have the ability to notify the NRC. They have to have the ability to do the evaluations or report to us and so on, and it's something they just don't understand. And so it's very difficult to implement, which then forces us to dedicate everything, which is also a very burdensome process where the bottom line is they will have a program, a quality program to design and manufacture that part for us that meets every intent of our program so therefore we're not altering the product. All we're doing is changing the method of reporting, or requiring some method of reporting that is difficult to implement.

VICTOR HALL: It sounds like you have all the tools to dedicate, but the bottom line is if you don't have the comfort level that they can meet Part 21, don't buy it. You can't -- I don’t see how you can approve them to be a safety-related supplier. You can say they're a supplier that provides products with certain quality attributes that you can take credit for in your dedication, and that's certainly typical under dedication, but if you don't have that comfort level, if they haven't passed your audit for it to meet Part 21, then I don't see how you can put them on your supplier's list.

TOM LOOMIS: And not to cut you off here, Marc, I think in this situation I think we need some help with regards to guidance on these issues. This kind of goes I think a little bit beyond the rulemaking here, but you're starting to hear the different concerns, so we've kind of raised it up here and here we go.

RICH MCINTYRE: Hey, Vic, this is Rich McIntyre. I'm a senior

reactor inspector in the Construction Mechanical Branch and we've -- we're doing a number of vendor inspections in international countries, and people are invoking Part 21 and appendix B on suppliers, and those companies that are accepting it are fully implementing a Part 21 program, and that's what we inspect against. Vic brought up the legalities of enforcement. That's a different issue, but as far as accepting and implementing, we're seeing that on all of the new reactor vendors that we're inspecting around the world. It's very clear, and if they're not inspecting -- I mean, accepting Part 21 and appendix B, then there has to be dedication activities.

VICTOR HALL: I see OGC in the background. He's probably cringing when I say legal, so I won't put you on the spot, Debbie. Let's move on to the next topic. Oh, sorry, Larry. We'll do Larry's comment and then let's move on, please.

LARRY CAMPBELL: Thanks, Vic. This is Larry Campbell, NMSS. Historically Rich is absolutely correct. The enforcement aspect cannot be initiated for, say an international procurement, but what -- I know over the years what we have seen is a licensee can go in, do a full-blown audit, quote, you can call that a commercial grade survey, you don't invoke Part 21, you got 30 critical characteristics, I'm just making that up. Probably that survey can be used to verify all of them, then the purchaser assumes Part 21. I'm not saying that's the way to go, but that is one method. And on another issue, if you look at Part 21, you've got Part 71, Part 72, they use terms important to safety. You've got Part 40. They don't use a term exactly. You've got Part 70, items relied on for safety. You've got Part 76. It doesn't invoke appendix B, but it does invoke NQA-1. So I think the terminology -- that part, I think, is something that needs to be

addressed. Thanks.

BUTCH BURTON: Thanks, Larry. Before we go, let me just pulse folks on the phone if anybody has a quick comment on the subject.

SID BERNSEN: It's Sid Bernsen, and I'd like to make a couple of observations. Number one, you know, 50.69 allows risk-informed reclassification of safety-related items into high and low safety significance and excludes the use of Appendix B for the low safety-significant items. I think we have the same kinds of problems that were discussed for non-power plants in the power plant area as well, and, in addition, appendix B really, if you read it, is clearly applicable to licensees and permit holders. It seems like you need to decouple the quality assurance requirements from Part 21 for sure across the board.

TOM LOOMIS: It looks like it's a ripe area for more discussion on this.

BUTCH BURTON: Right. And that's going to be my next question. Parking lot item?

MALE SPEAKER: Yes.

MALE SPEAKER: It sounds like [inaudible] parking lot item.

VICTOR HALL: Right. Thanks, Sid. It's good to hear you, too.

BUTCH BURTON: And let me just say that I am going to be pulsing the group as we come to the end of each discussion area to make sure I capture anything that needs to go to the parking lot, and I may need some help to characterize it correctly. So, I'm going to be putting down foreign suppliers. Is that too broad? Or do I need to bring this down a little bit? Marc?

CHRIS EARLS: Butch, I'd recommend you reference the topical areas, so in this case, number two. It'll be easier for us to summarize at the end.

BUTCH BURTON: Okay. That's good. Is this good enough? We need to characterize this a little better or are we good here?

PAUL PRESCOTT: I'm just wondering, I'm going to ask Tom and Robert here, from an operating reactor perspective and new reactor perspective do you -- is this an issue or is this more in the realm of the NMSS folks and their vendors?

TOM LOOMIS: I think we need to look at it a little bit further, because again, you know, I understood what Vic said with regards about putting safety-related -- defining it inside the purchase spec. I think we need to think about that a little further. It's definitely -- we'll expand the parking lot here to a Wal-Mart parking lot with a number of items here, but we can pick it up in the next meeting on that one. I think there's a way of getting around this with a guidance, making sure that it's clear that people understand. I don't think it's a real big issue for us, but we have to be real clear about this appropriate quality requirement.

VICTOR HALL: I think what we'll probably do is -- because I kind of expect to have a pretty big parking lot, so I think if -- but at the end of the day what we'll do is maybe classify our high/low and then go from there. I think from the discussion I've heard today I feel pretty good that I have an idea how we can go back and make this area a little better without too much more discussion, so I'd say this is a low priority one. So with that, let's move on to area number three.

ROBERT LINK: If I could just say one more --

VICTOR HALL: My apologies. Go ahead.

ROBERT LINK: -- comment, sorry. Again, this is related to a discussion we'll probably have later relative to scoping and what is a basic

component for at least fuel cycle facilities, and on page 10 in the paragraph under C's, first bullet, there's a comment that says, "for non-reactor applicants and licensees, the appropriate QA requirements per NEG appendix B management measures sub-part 10 CFR Part 71," et cetera, and I recognize you're just trying to provide some overview examples, but the -- when I see the words “management measures” I presume that it's a reference to a requirement under ISA requirements, which we must have management measures represented, which is -- those are, in our opinion, quality requirements. I'm not disputing that. They aren't necessarily -- I want to be careful not to draw the nexus, whether or not that means all IROFS, because we'll get into that discussion relative to a basic component -- I'm not disputing that we must apply appropriate quality assurance requirements to basic components, but that does not, in our minds, equate necessarily to our commitments in chapter 11 ISA submittals.

VICTOR HALL: I think it's a good -- that's a good lead in to our next topic, which is the lack of clarity on basic components, so I'm going to keep us moving here, guys, because we're a little slightly behind schedule.

[laughter]

We're going to be here until 8:00 tonight.

SABRINA ATACK: I love that Vic thinks that being behind schedule is going to be improved by the next slide.

[laughter]

VICTOR HALL: You want to take it, Sabrina?

SABRINA ATACK: Yeah, yeah, sure. Okay, so we've proposed some language to clarify the definition of basic component as it applies to non-

reactor facilities, specifically Part 70 facilities, and the reason at this time that it's limited to Part 70 facilities is because we've seen a large number of exemption requests from Part 70 facilities to change the definitions under Part 21 as they apply to their facilities to enable them to proceed with new construction in a manner that's in compliance with Part 21 and most convenient for their facilities.

The definition -- okay -- is on that slide. As you've stated previously, this is just some ideas. The language itself is subject to change and likely will change, but the concept is here for us to discuss. This parallels what we've seen in applications and exemption requests from Part 70 facilities, and the idea is that any items relied on for safety, IROFS, whose failure would cause you to exceed the performance requirements of 70.61 would be basic components if they meet the criteria in that definition. Two things to pay attention to in that proposed text is the use of SSCs, which are systems, structures, or components. Note that that's different from items relied on for safety, because IROFS can include administrative controls, whereas SSCs are hardware items, and also, the use of the term “diverse.” We want you to consider the use of redundant IROFS where applicable to not be -- for instance, if you had two redundant IROFS, two of the same item performing a safety function to prevent or mitigate the same consequence or accident, then those will both need to be basic components if there were no other IROFS in place to prevent or mitigate that accident, because you have to consider single failure criteria.

TOM LOOMIS: I'm going to turn it over to Janet on this one.

JANET SCHLUETER: Well, yeah, I'm going to -- oh, sorry. I'm just going to make a couple of general comments and then turn it to Bob. Just for the benefit of the broader audience, I know Sabrina is perfectly aware of this, but in

the fleet, as Bob and others have mentioned, there are some facilities that are tied to NQA-1. The others are not. And that does impact a lot of areas, this being one of them. But if you look at that language, just be careful also to remember that right now there is a proposed final 10 CFR Part 40 rule with the Commission that in many ways is a mirror image of what is currently in Part 70. So if you have concerns with Part 70 today, you'll need to relook at the Part 40 that comes out of the commission sometime in the near future, because there were many things that were done to that rule to try to make it look more like Part 70, because the fleet is licensed under either 40, 70, or 76. So we have 76 under item four. We have 40 under item four right now, but that's going to have to be revisited, I suspect, depending on what comes out of the Commission. So, just a process issue.

SABRINA ATACK: Yeah. That's a great comment. Thank you, Janet.

ROBERT LINK: That really speaks a little bit to, again, what Tom brought up earlier in terms of unintended consequences when we have multiple rulemakings going on and they do have impact on each other. One of the prime issues, I guess, the regulatory basis document brings up, and I guess I want to also, first off, recognize that we've had a dialogue with NMSS for some time now on this topic. In fact, FCIX over a year ago had a presentation, I believe by Sabrina, and there were follow-up questions that were posted. We've had some face-to-face dialogues to even further understand and clarify mutual understanding of that. One of the, again, basic issues that we need to wrestle to the ground is -- and it goes back to, again, basic component, and obviously then that means substantial safety hazard, at least that's the way I read it in terms of

the existing rule, which we would still say is appropriate. But that's where we get our first major challenge. Again, the definition of a substantial safety hazard, at least as it pertains to fuel cycle facilities, is not crystal clear, and that clarity, I think, is where we must start. If we don't have that, we're really lost from the beginning, because that's where we're going to be able to find -- the licensee obviously is obligated to evaluate them, their systems and components and what have you against that criteria. The -- I would say that we do not agree that 70.61 constitutes a substantial safety hazard. In other words, if you don't meet the performance criteria, that's a substantial safety hazard. We do not agree with that.

And IROFS are not created equal. You have intermediate consequences that I would argue are not substantial safety hazards. I'm getting a rash on my skin from a chemical exposure, which may meet the criteria under 70.61 as an intermediate consequence does not constitute a substantial safety hazard. So, there may be action standards. There may be IROFS that don't even approach that criteria, in our opinion, so again, that's really the -- kind of the hard efforts that we, again, mutually need to wrestle to the ground and evaluate, which gets back to getting a clear definition, force fuel cycle facilities as to what constitutes a substantial safety hazard, doesn't mean we have ignored it. Obviously we've been under Part 21 since its existence. But I'll be very frank with you, when we've done analysis and evaluations to see what defects could cause a substantial safety hazard, it becomes a very, very small number. One example is somewhat notorious, I guess, at least in our lives, and that's the hunt valve issue with the 30 B cylinders, where a defect was found by the hunt valves. Now, that technically isn't on our Part 70, because it's a transport device, but

when we try to look at those examples, at least in the fuel cycle facilities there, to learn from and to grow a better -- mutual better understanding, there are very few. So, that just, again in our minds, describes or at least maybe is the best example of, you know, what are we talking about here, what is the subset of components that we must apply this to.

Actually, I'm interested in the subdivision and I know the proposed language is just there to help understand an approach, but with the pending action under Part 40, actually what will happen in my case, I'll be a Part 40 licensee as well as a Part 70 licensee, where today I am only a Part 70 licensee. The language in Part 40, and I have not gone back to study this relative to the Part 21 issue, but I would hope that that becomes transparent, but because you at least are conceiving a possibility of dividing that reference within Part 21, Part 70 in one paragraph, Part 40 in another paragraph, then I as a licensee will have to deal with both obviously from a regulatory compliance perspective, and trying to deal with that, and make a reconciliation that, again, at the very least would require some guidance or understanding of what would be acceptable to the agency.

I also noted, again, in the proposed language on Page 14, there's no reference to substantial safety hazard, which again, I guess in my mind, this gets back to my comment earlier about the introduction, the scope change. Without that nexus, without that direct reference, you know, you are in fact changing the scope, at least in our perspective, you know, in a noteworthy way. If that's intended, I understand that and we can talk about that, but if it's not intended as stated, at least in the introduction, then I would suggest that, you know, reintroducing the substantial safety hazard basic component nexus is

appropriate, and then work on, as I stated before, creating better guidance as to what constitutes a substantial safety hazard in the context of fuel cycle facilities.

SABRINA ATACK: Thank you for the comments, Bob. I would like to get a little bit of clarification on your example of the intermediate consequences that maybe are more restrictive than a substantial safety hazard. The skin rash you referred to, personally, I don't necessarily see that that would be an intermediate consequence, but maybe I'm not understanding it properly, but if you could provide us any guidance or examples on what criteria you think would be a substantial safety hazard, or why the intermediate consequences are not within that realm, I think that would help us understand the concern a little better.

ROBERT LINK: And I'm confident that we, you know, as a group would be very willing to enter into that dialogue with you. I'm sure we have a number of -- a few examples of -- obviously in the interest of time and efficiency, we probably want to move on, but we stand ready to talk about that. We would love to engage in a constructive dialogue relative to even drafting what constitutes substantial safety hazard. We can clarify more examples and try to differentiate whether or not even high consequences could constitute a substantial safety hazard, because at least some of us would argue that that is even an issue and indiscretion.

BUTCH BURTON: I think, yeah, if for time's sake, we do want to try and move on. I want to touch on folks with the phone. Folks on the phone, any quick comments on this?

MALE SPEAKER: [inaudible] --

BUTCH BURTON: Name and affiliation, please.

MALE SPEAKER: [inaudible]

BUTCH BURTON: Oh, he's breaking up. Hang on one second. You're breaking up on us a little bit. Can you start again and give us your name and affiliation?

MALE SPEAKER: [inaudible]

BUTCH BURTON: Wow.

MALE SPEAKER: I believe that's just the person that doesn't have their phone mute.

BUTCH BURTON: Oh, is that what's going on?

MALE SPEAKER: It's doing that all along.

BUTCH BURTON: [laughs] Okay. Well, let me say it again, for those of you who are not speaking, please put your phone on mute, because we do pick up some of the background. Okay, so I'll ask again. Is there anybody who does want to speak, make a comment?

MALE SPEAKER: [inaudible]

BUTCH BURTON: Okay. All right, well I think we're going to move on. I have a --

ROBERT LINK: I have one more issue, if you don't mind, and then this more in the context of clarity, because at least when I read number three on Page 14, I could interpret those words as saying sole IROFS are basic components. Now if that's what meant, that would add some clarity. Sabrina and I thought, if I understood your comment earlier, you were talking about when you mentioned the redundant IROFS, I thought you implied and not stated that both redundant IROFS would be basic components. Again, we would disagree with that perspective respectfully, and that's again, when we read the wording

here, if you are describing a sole IROFS as a basic component and then couple that with at least from our perspective a sole IROFS were in a high consequence event, we may be closer than farther apart. I'm not saying we're there yet, but I think we're honing in on what we might mutually agree as what might make sense in certain cases.

The other aspect, and you referenced the use of the term SSCs, and I respect your insight to the realization that we have many administrative IROFS, and I presume, again, by your comment that you are focusing, you want to focus this on hardware. Although the scope of Part 21 as I read it is services as well, and what constitutes a service relative to an administrative control is cloudy. I will just kind of leave it at that for now. So -- and also, is the wording, and I don't necessarily expect an answer right now, but for further discussion, the way I read it, SSCs could be taken credit for in the evaluation as to what constitutes a basic component, and those may not be IROFS. They may be simply features of the facility that are highly reliable, and while I think that's an appropriate evaluation characterization , that's again not clear, and whether we will put that in guidance or in the rule words would have to be further discussed.

SABRINA ATACK: I'm sorry, could you repeat your last statement, which items you were talking about, the services?

ROBERT LINK: Pardon?

SABRINA ATACK: Can you repeat the last part of your discussion that you thought was --

ROBERT LINK: The reference to the SSCs?

SABRINA ATACK: Yes.

ROBERT LINK: Okay, in the wording, we say, "and whose failure

would result in a condition in which no diverse SSCs are available to assure" boom, boom, boom, and there's no statement there. There's no reference to those SSCs as IROFS. They are simply what they state, a structure system, a component. There's no pedigree is what I guess I'm characterizing here to be clear. So, and that infers to me that the SSC, if available, which kind of looks reliable, available, could be accredited in some form in that assessment. And again, I believe that may be appropriate, but it's not clear to me that that's what you meant.

SABRINA ATACK: Okay, I think there are definitely some opportunities to improve the language and the clarity, and we'll take some of those back with us, and work on it, and get some feedback from you guys to modify. I think a couple of things I can address really quickly, there may have been a little room for improvement in our earlier discussion. Yes, it is the intent to exclude administrative IROFS from the statement. I think we do need further discussion with respect to what a substantial safety hazard is. I think that keeps recurring, so I think we'll probably put that on the parking lot. We may need to clarify the difference between services and administrative IROFS. I think in excluding for administrative IROFS, it is the staff expectation that things like "see and flee" would not be considered basic components and would not prevent a hardware item from being a basic component, but safety related service -- well, I'm not going to use safety-related-- the services such as welding that would affect the integrity of an IROFS, if it's necessary to meet the performance requirements. Well, that would be a basic component. So like I said, there's definitely room for clarifying the language, but hopefully that addresses a couple of our topics.

ROBERT LINK: Yeah, so you may want to add --

BUTCH BURTON: Yeah, okay, couple things. We have four more topics that according to the agenda we want to try and get through by 10:30, and we have less than 15 minutes. So, I hope we can get everybody's cooperation for the final four, that we can move through these fairly quickly. We have a fairly low threshold for putting things in the parking lot. I mean there's going to be plenty of opportunity to discuss a lot of these topics further. So with that, okay --

ROBERT LINK: That definition is substantial --

VICTOR HALL: Yeah, Butch, let's just add, if you don't mind, I'd like to just add two parking lot items for this area. I'm not trying to multiplying them, but so if we add -- okay, so we already have that one now. Okay, great, perfect, and then the next one would be SSH, yes. We already had it. I'm slow, sorry.

BUTCH BURTON: Just put SSH?

VICTOR HALL: I would write three again, because I think SSH is separate, a separate topic, a separate piece we need to add, that we need to address.

BUTCH BURTON: Okay, but it's all going to be captured under topic number three?

VICTOR HALL: Yes.

BUTCH BURTON: That's correct? Okay, so that's how I'm structuring it. Anything else?

ROBERT LINK: Well, I think the SSC issue also deserves some further dialogue.

BUTCH BURTON: And so, if I put just SSC and SSH, that's okay?

ROBERT LINK: Yeah, I think we'll know what that is, yeah. C as in Charlie.

BUTCH BURTON: Oh, sorry. C, okay, we'll sort all that out later. Anything else for the parking lot? That's good. Okay. All right, so you're ready to go to the next one?

SABRINA ATACK: Yeah, and just quickly, before we move on. The parking lot is fine, but I did want to clarify that your comment where you feel that sole IROFS, the high consequence events would be more appropriate as basic components. I do want to clarify that's not what we were saying in the definition. The definition as proposed would include things beyond sole IROFS, because you have to exclude for administrative controls, and also for redundant IROFS. So, if you think that we are on the same page, I just wanted to make sure you understood that we may not be as close as you hope we are, but --

ROBERT LINK: No, I did understand that.

SABRINA ATACK: Okay.

ROBERT LINK: [laughs] And we're clear that my interpretation was not what yours is. That's fine.

SABRINA ATACK: All right, thank you.

[laughing]

VICTOR HALL: Butch, should we move on to number four?

BUTCH BURTON: Yeah.

VICTOR HALL: Let's roll on to number four.

TOM LOOMIS: All right, Butch. We'll do our best to be cooperative here. I want to begin with the clarification of point of discovery here and a discussion on that one. Is the intent here that when we enter the issue into CAP,

that is to start the 60 day clock? Is that basically what we're driving towards here?

VICTOR HALL: That's the idea and I would argue that it's what it says now.

TOM LOOMIS: Yeah, all right, now what -- We're having a little problem with that, because fundamentally it's like from the time you put it into -- you're coming with a couple of different issues here. You'll either A, discourage people from putting into CAP or, you know, B, you'll have this sort of tight fit to the regulation, I think is what you want to dive this -- let me just give you some examples. We run up against a lot of issues, whether they be reportability under Part 21, 50.72, 50.73, where you really have to sit back and you have to think about it, and you have to move along. A classic example would be like design analysis. I'll just throw something out there. We'll call it design analysis acts. You know, you really at times need to get back, run analyses again, you know, do a lot of different things before you really can tell, do we have a problem or not, is there really an issue here? You know, are the temperatures of the fuel rod, you know, where we need them to be? So, it's like the idea of once you put it into the CAP system, you click off, the 60 day clock won't work for us, you know, and 72/73 language, they use the term firm evidence, and I kind of -- for those familiar with that, it's in the NUREG-1022. It's firm evidence, you know, and how do you define firm evidence? And I go back to the definition of pornography. Boy, I can't give you a definition, but if you showed it to me, I could tell you. You know, and I would suggest maybe we move to something that, you know, let's encourage people to be expedient in their discovery and their movement of pointing out Part 21 problems, but we don't want to, once it goes into the CAP

system -- and you may think that there could be something, do you start the 60 day clock? It just doesn't work for us, and then the end what you're going to do is you're going to have people spending hundreds of thousands of dollars, resources completely driven off of where they need to go to solve an issue within 60 days. Now, fair is fair. If somebody's dillydallying about it, and you know, somebody puts it into the CAP system, let it languish, let it just lay around for six months, then by all means I can understand somebody coming in and, you know, writing up a violation on that, but we need time for discovery on that. And Paul, do you have a comment on that one? I see you do. Okay.

PAUL PRESCOTT: As you're well aware, we've had inspection findings related in this area, not so much -- not with licensees, but with -- the issue has been with vendors, and you know, there's history here. There's a history here. Before we had issues with people taking one, two years to do an evaluation and file a report to NRC, and that's why we put time limits on. I'm certainly willing to hear some ideas on where we go with this, but I think if we leave it fuzzy and in the air with, you know, some kind of firm determination, or you know, we have justifiable reason now, you know, then we're going to end up with the same thing, with people taking in the front end instead of the back end, you know, a year, two years to perform the evaluation, and I would argue that Part 21 already in a way allows for this time to evaluate where we allow to licensees, vendors, to provide an interim report, as long as it's within, you know 60 days from the point of discovery. So you know, again, you know, I mean today is to listen to some ideas. But you know, that's where my thinking is right now.

TOM LOOMIS: Yeah, we just don't want to be putting a lot of

interim reports on the docket on issues as well. I mean that's another sort of situation we don't want to go into. I know there's a degree of fuzziness about it --

PAUL PRESCOTT: [affirmative]

TOM LOOMIS: -- but I tell you right off the bat, if you say it goes into CAP, I think you're discourage a lot of CAP use at that, and I think that they're -- and I think we're willing to take a sense of reasonableness, and maybe the language and the guidance should be we expect full expedience once an issue is identified, and you know, if that -- and use whatever terms you will. If we see that you're dogging it, we're going to write you up, and we take that as a challenge. But I mean I can pull out a number of issues where, you know, we put them in the CAP. We put them in. We [unintelligible] the day. We've got a problem. We emphasize very strongly where I am, get into the CAP system immediately, but we don't want to be clicking off a 60 day clock, and forcing a vendor to bring people in over Christmas to be doing -- and this is what happens. I mean you'll be bringing some more vendors in to be running code on Christmas day. No. No. We have to use judgment.

VICTOR HALL: And Tom, coming at it from -- looking at this from issues that vendors face, because this is really where this was driven by. There's two pieces I think that can really be clarified by linking to the problem identification resolution to the CAP. One, you've got -- you get rid of this term "completion of documentation, first identifying the existence of a deviation," right, which is I think a part of the root of the problem. You get rid of that term and you create a term. For us in this case would be, you know, when you first put it in the PI&R system, that it's going to be universal for licensees and all vendors, because everyone's created a little differently. And without that definite term that

is equal for everyone, it's going to be tough for you to say when the point of discovery starts, but that's the first piece. The second piece is a tie to the Appendix B program, and that's where I think vendors really fall short in recognizing that what their Appendix B program does in both identifying nonconformist reports and corrective action reports must feed into Part 21. And so, there's a huge benefit in calling out the Problem Identification and Resolution Program in Part 21, so that they know. Hey, you know what, that stuff I'm doing under Appendix B has got to get evaluated under Part 21. So, there's a twofold benefit there, but I do agree that we -- because I'll tell you straight up, I don't know how the Part 21 processes work. The licensees -- we haven't looked at them, and licensees since what, '91, at least from our side of it. So, that's a piece that I'm very receptive to and I want to hear what you think it would -- or how this would affect licensees, because you certainly don't want to create unintended consequences in reducing the number of CAPs in creating unreasonable deadlines. But the benefits to the thousands of vendors out there I think would be tremendous, and be able to define when the point in time it's going to be. It's got to be that, and tying that link to Appendix B.

TOM LOOMIS: I understand what you're saying. I could see vendors -- let me just say that if we find an issue with a vendor, they better tell us but quick, and if we find that a vendor has not been very fast, there are issues, and they may not be one of our vendors in the future. So, we are very tough on our vendors about the problem identification and resolution. This is one we'll have to talk through a little further.

VICTOR HALL: Okay. Yeah, this is one where -- yes, we want to give time for folks on the phone, because that's where hopefully vendors will

chime in, too.

TOM LOOMIS: Let me just say, Paul, we're okay with you being tough on these people if they're dogging it, okay?

VICTOR HALL: And that's what drove this. I mean this is in here because a good chunk of our inspection reports identify this problem. So, Robert, I thought you --

ROBERT LINK: And I won't belabor this one, but, again, we agree basically with the concept that we need further clarity, and use of the words that are in there already in terms of problem identification and resolution, we've had no qualms with. Be careful with the Appendix B references. Be careful with the Part 50 nomenclature. We are not committed to a corrective action program in our license. We have commitments that head to a problem in our identification resolution process relative to part of our processes. Now, I want to be very clear. Our product is a different issue. We have commitments relative to our customers with Appendix B for our product. I'm talking about our process, and that also needs to be understood and clarified. And I think that all can be done within the guidance that is proposed, at least as I understand the draft reg guide basis, okay.

TOM LOOMIS: And, again, just reemphasizing on where Bob went, I think this is a guidance issue as well. I think we can handle this through guidance.

VICTOR HALL: Let me ask a question. If you agree that we can improve the language initiation as a completion of the documentation first identifying the existence of a deviation, which I really believe we can, and this is a rulemaking issue.

TOM LOOMIS: I'm sorry?

VICTOR HALL: If you believe, which I strongly believe, that we can improve the language that's in the definition now of discovery that says it's a means to completion of the documentation that first identifying the existence of a deviation. If you believe we can improve that language, which I believe we can, then this will be a rulemaking issue.

TOM LOOMIS: I like the language the way it is, quite frankly, because I would say when we know, boom. We've got that problem that goes into the CAP system, start the clock. We throw the gauntlet at that point. I like the language. And then we have, you know and again, I think where our issue is, is in the discovery here, and I think that's where, you know, I think you guys once we throw it into CAP, you want the 60 day clock. I feel as though we should have a reasonable period of discovery ahead of time, and I like the language the way it is written right now. Maybe we can emphasize a little bit in guidance, a little bit more how you feel about it. Maybe you can put in there, we've noticed in some cases vendors have not been as quick in the problem resolution with whoever, the end user, and put that in there, and make no uncertain terms that if we catch you, we're going to write you up, something like that. Language just like that, right? Write them up.

PAUL PRESCOTT: I think we're good. I think I understand where you're coming from, and I don't see why this can't be discussed a little bit further.

BUTCH BURTON: Okay, comments from folks on the phone, on this topic?

VICTOR HALL: Or in the room as well.

BUTCH BURTON: Yeah, folks in the room also? I don't know if

you had designated anybody.

VICTOR HALL: What I'd love to hear is some feedback from some vendors who say, "Hey, I don't like this definition because it's unclear." "Yeah, I love it." I'd love to hear some feedback from some vendors out there, and what your opinions are on the point of discovery and how clear it is to you.

JULIE KEYS: I think the definition -- here we go. Thank you. I think the definition's clear. It's the implementation of that definition you're having issues with, which is the exact reason that guidance helps. You know, you can write a rule, but you're never going to write it to the level of detail that you're going to get the implementation of that clear. It's never -- the rule's never going to be that detailed, so you're still going to need guidance anyway to have clarification of that. So, that's my opinion.

FEMALE SPEAKER: Julie, can you say who you're affiliated with?

JULIE KEYS: I'm from URS.

FEMALE SPEAKER: Okay, thanks.

JAY SILBERG: Jay Silberg from Pillsbury, the law firm. We've been through this with a number of vendors. We thought the definition was clear. The staff and the inspectors thought it wasn't clear. We've reached an accommodation to deal with the problem, but the guidance really could explain what you guys have in mind. I don't think you need to change the rule.

VICTOR HALL: What did you really think, Jay?

[laughing]

Thanks, appreciate that.

BUTCH BURTON: Okay, oh, one more, one more real quick.

CHARLIE BROWN: My name is Charlie Brown. I work for a PPL

Susquehanna LLC. I personally like the new rulemaking words and -- or the new words in the Part 21. I have had a lot of problems with vendors who constantly explain to me why they haven't determined why it's a problem yet or not, and most of the time it's foot dragging.

BUTCH BURTON: Sorry about that, folks on the phone. Okay, other comments, either here or on the phone, and is there anything I need to put in the parking lot? What's the general consensus here? Anything? Vic?

VICTOR HALL: I was just not adding to the parking lot, because I think we're pretty clear that we don't agree.

[laughing]

And I think it's clear. So, I don't think we need to belabor it.

SABRINA ATACK: And just before we move on, I just wanted to pulse the non-reactor folks, to see if there were any issues with this type of language, you know, the problem identification resolution. I think that appropriately encompasses the range of programs that can be implemented, but I did want to see if there are any specific concerns with this concept from the non-reactor folks.

ROBERT LINK: Just other than, again, providing the guidance as to when that clock starts relative to how we apply that in our P&IR basis. I think we can, again, I think we can do with that in guidance land. I do agree that further clarification is appropriate.

JANET SCHLUETER: Yes, and just on behalf of those non-reactor and non-fuel facilities that may not be thoroughly engaged yet, I wouldn't take their silence at this point in the meeting as agreement; stating the obvious, but perhaps important.

VICTOR HALL: All right.

BUTCH BURTON: Ready to move on, then?

VICTOR HALL: Let's move on, thanks. Should we tackle one more before break? Butch, what do you think?

BUTCH BURTON: Yes.

VICTOR HALL: Okay.

BUTCH BURTON: We can either make sure we cover all the topics and go a little later, or stay on and try and catch up a little bit later, whatever group wants to do.

VICTOR HALL: Okay, we'll keep chugging away. All right, on to number five, clarification of deviation and delivery. Tom, I'll let you lead the discussion.

TOM LOOMIS: Sure. Vic, question for you on this. Was this an attempt to clarify the definitions? Is that what we're trying to do here?

VICTOR HALL: It's really -- I think the definition as right now do us a disservice in the way in what pieces are where. It's the piece of a decoupling delivery from the definition of defect, which I think does us a disservice, and so I think by shifting stuff around in this case is where we can provide more clarity.

TOM LOOMIS: Well, one of the ideas that had come up to us yesterday was that why don't we just put together a flowchart on this rather than be moving definitions around and so forth. Quite frankly, I was a staffer here in '78 when the gentleman wrote the infamous memo about importance of safety is equal to safety related, and I don't know that we've ever really sorted that issue out completely on that. So when we go in there and we start, you know, changing out definitions and so forth, I'm kind of concerned about, you know, the

chaos of that it is going to create. Maybe a flow chart helping us through on this, and then also we don't have to talk about it here, but the -- you know, the literal compliance issues you had here about the definition of defect screens out delivered basic components; we were a little bit confused about that one.

VICTOR HALL: Well I'll tell you, it's the flowchart that got me going on this piece, because when you draw the flow chart out and you ask yourself where does delivery happen in the process, where does it affect when you're looking at whether it's a defect or a deviation? That's when I realized your concept and delivery is in the wrong place, and it's really by putting a flowchart together that I was looking through the definitions, and it just does not match up, doesn't mesh up.

TOM LOOMIS: Maybe we should just then look at the flow chart, you know, and the subsequent meeting, and see where we're going with that one. I mean I think with Part 50, guys, we're okay with delivery because we know when it comes in for the most part, and then some people didn't agree with me on that. But when it comes in, and we sign them into acceptance, and it's ours, and it's on our shelf, you know, it's ours.

VICTOR HALL: And that's a second piece, because there's really two pieces. It's that decoupling, and the other piece is the what is acceptance, and acceptance is receipt inspection, all right? Everyone does a receipt inspection. That's certainly not clear in Part 21 and that's where we can do a huge service I think to the industry by clarifying that acceptance is what constitutes delivery [inaudible] --

PAUL PRESCOTT: It kind of goes, Tom, it's the threshold of pain. I kind of reached in on this one, because when I have to go on an inspection, or

we have to take several phone calls related to, “hey, well I think he needs to do the evaluation. No, you have to do the evaluation.” That’s kind of where I’m looking to try and clarify it, and I felt it was necessary that this one be put on the table for clarification, because we’ve had so many vendors go, “No, the ball’s not mine. It’s the licensees,” and the licensee goes, “No, the ball is not mine. It’s the vendors,” and so we’re trying to provide clarification where that point is. Because I mean have we gone to OGC and asked for what the clarification is? Yes, we have, and for us it’s if the licensee has received it, and accepted it, that’s the point when the licensee gets it. If they haven’t accepted it, they ship it back, or you know, they haven’t completed receipt of inspection, then it’s the vendor’s responsibility. So, you know, we had to find that legal cutoff, because it was coming up so often, and you know, the ball was getting thrown back so many times, back and forth. And so, that’s why we felt that this one was a critical one to put out there for clarification.

TOM LOOMIS: And that's a good one for guidance, because I don’t think you -- because, you know, you’re taught different products, engineering, evaluations. I’m right there with you and --

PAUL PRESCOTT: All right.

TOM LOOMIS: -- believe me, I have been on the phone arguing with vendors who [unintelligible], you know, and in my case, being a licensee, you guys are telling me no. So, I’m right there with you.

PAUL PRESCOTT: Okay.

TOM LOOMIS: You know, we’ve worked for the same company sometimes. So, it’s -- yeah, it’s a good clarification issue, but I would have -- Bob has I think a little bit of perspective on this as well, not being [inaudible] guy --

ROBERT LINK: I guess it's more confusion than clarity, because if I read, again, the words at the bottom of Page 19 where we say, "Therefore an item is delivered when purchasers accepted the item following the completion of receipt inspection." And I thought, Paul, you were pretty clear in your comment just now, that also said that, but when I looked at the defect means proposal, that clarity went away. You know, I mean you're excluding or your striking --

VICTOR HALL: Right.

ROBERT LINK: -- language that actually would help that clarity, in my opinion.

VICTOR HALL: You're striking it because the concept is important when you're talking about deviation. If you talk about a defect, that's when the evaluation has already been done, right? You're starting with the premise of deviation. You evaluate that. If that isn't SSH, then you have a defect. So, the concept of delivery really is only relevant when you're talking about a deviation. You're not going to have to perform an evaluation until something is a deviation delivered. That's why this does not belong in the definition of defect. Why? The concept of delivery belongs -- related to deviation and why we should link it to acceptance, to receipt inspection. That's a thought.

ROBERT LINK: Then maybe it was my misunderstanding as to why it was in this section even. Don't get me wrong, the definition of defect is a critical part of the whole matrix of understanding, but when we're talking about, you know, the concept of delivery, and now we're redefining defect, those two, in my mind, are two different things.

VICTOR HALL: Right, and what's probably missing from this to make it clear, is what the flowchart would look like, and what the rest of the

regulation would say regarding delivery, and deviation, and acceptance.

ROBERT LINK: For my clarification, what flowchart are you referring to?

VICTOR HALL: Oh, it's the flowchart in my head of what the process would look like.

[laughter]

Didn't you get the memo?

[laughter]

ROBERT LINK: Crystal clear.

VICTOR HALL: But it wasn't in the discussion of talking about what -- because the flowchart, you know, would paint the picture of what this process is going to look like in evaluating and reporting, and that's where I think you draw out some of the flaws that are in regulation right now. So, that's the fun. Maybe what we need to do is take back, and clarify what the rest of the regulation might look like if we do a better job on clarifying the rule. So, I think I might be able to convince you guys on this one.

BUTCH BURTON: Okay. Are there comments in the room?

FINDLAY SALTER: This is Findlay Salter from South Carolina Electric and Gas. Just so I understand correctly what you're attempting to do here, are you proposing to strike the words from the definition of defect, and then add some kind of words in the definition of deviation that allude to acceptance by the purchaser?

VICTOR HALL: Likely not the definition of deviation, but certainly in the process that describes when you will be required to evaluate, because deviation I think is pretty darn clear, right. You send something that wasn't what

it said it was going to be, and that needs to be evaluated. Now, if that item was delivered, it was accepted, then the evaluation needs to proceed, and so that really belongs in the requirements of what has to be done when you have a deviation.

FINDLAY SALTER: All right, thank you.

BUTCH BURTON: Okay, other comments in the room? Ah.

ED BAKER: Ed Baker, Talisman International. Vic, as you craft that language, be careful of the unintended consequences that you don't cause the vendor to think only about the immediate supply of that item versus previous supply --

VICTOR HALL: Right.

ED BAKER: -- because you could end up in a circumstance where they -- they haven't supplied it this time, but with extended condition they're going to have to go back, and look, and say, "Okay, does this deviation exist in anything I've already supplied?"

VICTOR HALL: That's a good thought and something I always keep in my mind when people talk about extended condition, and certainly in the guidance we would really want the tie, at least in the Part 50 world the tie to the Appendix B world, but you're always taking, say, a return, and you should be feeding that back into your corrective action program, to look at where that was supplied, and how that affects the rest of what you supplied. So yeah, I appreciate that.

DAVE KEHOE: Dave Kehoe, MOX Services. A little reading of your proposed defect definition could lead one to interpret that to mean that every deviation identified during a procurement of an item, construction,

maintenance, modification activities would require a substantial safety hazard evaluation. Was that your intent?

VICTOR HALL: Certainly not the intent, but -- I don't follow. If it's a deviation, it's --

DAVE KEHOE: The words are a deviation in a basic component that could create a substantial safety hazard. It's a deviation and the only way to confirm it couldn't create a substantial safety hazard without other screening criteria such as delivery, would be to do a substantial safety hazard evaluation.

VICTOR HALL: I guess it depends on how you define the process of what needs to be evaluated.

DAVE KEHOE: So the intent would be in the guidance document, to provide process guidance that would help us define [inaudible] criteria.

VICTOR HALL: Well, it'd certainly be more guidance and it'd certainly be more information in the guidance document, but I think the regulation could provide the words for a flowchart that describe when the deviation must be evaluated.

DAVE KEHOE: Thank you .

BUTCH BURTON: Other comments in the room first? Okay. Folks on the phone? Comments?

SID BERNSEN: Sid Bernsen again. One of the problems that I see is that we've been flowing this requirement down too far. Part 21 was really intended to apply to defects that might exist in a facility that's operating -- a licensed facility that's operating, and not necessarily a defect that perhaps a computer program supplier to an engineering analysis group might be using, that they haven't ever delivered to their customer. In other words, defects that are

never incorporated in a facility where the safety hazard is present really weren't intended to be covered by Part 21. I think some research into the [inaudible] of Part 21 would be helpful in simplifying this problem.

BUTCH BURTON: Okay, thank you, Sid. Others on the phone? Okay, we're about to wind this up. From the discussions, anything that I need to capture in the parking lot or further discussion?

VICTOR HALL: I think, if anything, it's to take back to -- I would like to be able to provide more language. I wonder what the rest of the language might look like regarding this, and take a crack at that, and I think that could provide more clarity to folks in what this might look like.

CHRIS EARLS: I think what might be helpful too is, you know, maybe informally draft out what this flow chart would look like, and compare it with the existing wording, and see if that, you know, if that could be -- if we can do it through a flowchart, through guidance with the existing words, and then that simplifies the exercise, you know. But I think it would be helpful in our subsequent discussion if you just rough out that flowchart and just kind of compare notes and see where that -- that may help us better understand this as well.

VICTOR HALL: Yeah. Quick funny story; we did a training session with our vendor inspectors, and I kind of gave them the quick spiel on what I've been working on, and how we might fix Part 21. And this is one of our good discussion topics we've got going. The first thing we did was we busted out the flowchart chart -- and we wrote a flowchart. I'm going to just go try to find that the break, and see if I can find it. Okay. You want to go for any folks on the phone, or are we going to --

BUTCH BURTON: Yeah, I think we've gone through one time. Anybody else on the phone? No, I think Sid what was it. Okay, we are running obviously a little bit behind schedule. Did you want to take a break now or --

VICTOR HALL: I see some nods, so let's take a quick break?

BUTCH BURTON: Yeah. Normally they were going to be 15 minutes. You want to take 10? Okay, so let's try and meet back according to this clock. I'll say about five of? All right, thanks.

[break]

BUTCH BURTON: Okay, welcome back. Went a little over our break time, but I think in the long run, it'll be okay. We're going to pick up with topic number 6. Go ahead, Vic.

VICTOR HALL: Thanks, Butch, I appreciate that. All right onto topic 6, Evaluating Reporting Responsibility, which is one of the things we touched on briefly in the previous topic of who has responsibility. One way I always ascribe Part 21 responsibility is it's almost like tar. Once you step in it, you got a piece of it. So you hear the discussion on -- between licensees and vendors. Well, they've got it, we've got it. Both pieces, both parties have a piece in it. That's not necessarily what this piece is about because I think we could do a really good job in reg guides describing my view of this tar, of both parties have a responsibility in it. The bottom line is the NRC wants a certification if there's a defect.

What I think we're seeking to clarify is a gap in the regulation right now that there is no responsibility for a customer to communicate down that they have identified the deviation, which, if I'm supplying something to you and you don't tell me, I may not know to enter this in my corrective action program, to

enter it into my Part 21 program and make that notification out.

I think good business practice certainly would carry that through. In parts of Appendix B, you could argue would require you possibly to notify the supplier. But it's not codified in part 21 that you may have this responsibility. And something we identified here. Having said that, we thought about what if we added to rule that you were required to notify down by deviation. And I think the general consensus was that's a heck of a burden, because every time you have a deviation, you're required then to notify down. That was how we came out with it. I can't imagine you'd argue with me on that one, but I'd love to hear your thoughts.

TOM LOOMIS: No, you know, I think it's a guidance issue. You know, I'm not quite sure making it as a part of rulemaking. I mean, guidance is a real good way to handle this. I would probably think of stepping in another substance with Part 21, but it's -- this last example here, I think this is a beautiful issue for guidance, you know. I think you have an issue there with regards to communication. I think we all need to make sure we're talking with our vendors and so forth and we can do that in the guidance document.

VICTOR HALL: All right.

BUTCH BURTON: Other comments in the room?

ROBERT LINK: We'd probably agree -- say again the nomenclature issue. The guidance needs to be respectful of that.

BUTCH BURTON: All right. Good. Others? Here? One from Mr. Baker.

ED BAKER: Ed Baker, Talisman International. Vic, I've got a question on the language you're using on 21 and then again in the first paragraph

on page 22. In the third paragraph on this topic under Definition of Regulatory Problem, you know, there is the potential for a substantial safety hazard. And as you point out in this paragraph, while the licensee who finds the deviation may determine it's not a substantial safety hazard, as you point out, it could be a substantial safety hazard for somebody else. So, what causes me concern is the language in the first paragraph in the second sentence where it talks about the requirement would likely cause additional burden with minimal safety gains. I don't know how you reconcile those two thoughts.

VICTOR HALL: The additional burden would coming from requiring a licensee to communicate down of the deviation.

ED BAKER: I understand that part. I'm really trying to reconcile the thought on the previous page where it could be a substantial safety hazard. And then on the next page you say "minimal safety gains." You may want to look at the language and see is that really the argument that you want to make? But to me, they're inconsistent.

VICTOR HALL: Okay, I see what you're saying.

BUTCH BURTON: Thanks, Ed. Other comments in the room before I go to the folks on the phone? Seeing nothing. Okay, folks on the phone, any comments on item 6? Okay. Hearing nothing, I will just pulse Vic, anything for the parking lot?

VICTOR HALL: Think this is an easy one again. Start an easy one and then we'll go to the harder ones.

BUTCH BURTON: [laughs] Okay, so we'll go to item 7.

VICTOR HALL: Item 7, the deferral of evaluations. The issue here is an issue you see pretty much in every inspection. It's -- as a vendor inspector

-- it's the out called the punting of partner responsibility. If a vendor determines that they don't have the capability to perform an evaluation, they're well within their right for 21 to notify their customers of, "Hey, I have this deviation. I can't evaluate it. That's yours now to evaluate it."

The gap that we've seen is that it's done all too informally and certainly does not make it clear that the licensee then has the responsibility. So a classic -- if I give you an example was an email to Tom and say, "Tom, I'm adding bolts and this bolt we supplied was not the ASTM grade that we said it was." End of message. And then say, hey, that fulfills my 21.21(b) responsibility. And you know what? They can probably make a decent argument that it might. And that's certainly not acceptable because it's got to be clear. It has to be clear that you, then, have that Part 21 responsibility. And that was the philosophy behind this topic.

TOM LOOMIS: And then we would argue over the issue of delivery. And so I think this one kind of falls back on the other issue of getting in delivery, like the discussion then would -- and said, "Okay, who has responsibility under the rule?" We'd go to that flow chart in your head. And we would say, "Okay, if we looked at block number 4, it's your responsibility. You guys are going to handle it." You know, when I looked at this and I saw that you wanted to write in here a whole bunch of items that we should be communicating with each other, I think that's a little overly prescriptive. I think hearing you talk now, I think this is more an issue that we need to be clear on in discovery. And once people understand -- or excuse me -- delivery. Once we know who has responsibility of that component in the chain, then I think we'll resolve that. Issues with regards to the type of communication, I think, is what I read into this. In particular, on item

number 6, we don't need to talk about that in a rule, because we'll drive to whatever information we need to evaluate that issue. I think more the issue of delivery as to who has the ball is more, I think, what you're driving at here, if I understand this right. If I'm reading you right.

VICTOR HALL: I think in this case we can assume that the item has been delivered and accepted.

TOM LOOMIS: Okay.

VICTOR HALL: If we assume that, it's the communication that happens after that, which has been inadequate. We've seen plenty of examples where it's been inadequate from vendors to their customers, not necessarily directly to the licensee, but it could be from a sub-supplier to another vendor. And that's where the communication has really fallen short in ensuring that the entity above them realizes that one, they have a deviation. Two, they've got -- then have partial responsibilities.

TOM LOOMIS: We're talking sub-vendors?

VICTOR HALL: Any vendor. It's the communication that comes from a vendor to their customer.

TOM LOOMIS: See, I think from a licensee from Part 50, we don't have really a problem with this. It's more about defining who owns the product at that point, under Part 21. So for Part 50, I'm not seeing an issue. Sub-vendors might be dealing with that, that they need to talk with each other about that. You know, what the impact on us is Part 50 is -- this creates, you know, a problem when, you know, you have all this additional information now that these people have to supply to us. Quite frankly, I think they give it to us now and, you know, at what point, at least for a Part 50 guy, I mean, do you stop with this? I mean,

how many more additional items, you know, can you throw into a rule on this? But I'm sort of hearing it's a sub-vendor issue. Am I picking that up right? Between vendor and vendor? Because, again, from a licensee viewpoint, once we know there's a problem, then, you know, we get the information we need.

VICTOR HALL: Well, I guess the problem is not knowing when you get the information. It's when there is a clear deviation where a vendor is taking the opportunity to report up --

TOM LOOMIS: Yes.

VICTOR HALL: -- what they're doing, so -- informally, either through an email doesn't communicate that this is a deviation -- calling that a deviation, and there's a Part 21 responsibility associated with that.

TOM LOOMIS: That's an education issue. If somebody hints, well okay, let's go back to the CAP process. If the CAP process works right and you don't discourage entering these type of issues, which we were talking about before -- if vendor from -- Vendor Y says, "We think we might have an issue with this," that goes right into the CAP system for evaluation. That's the proper way that the CAP system should work about it. And then at that point, we'll drive the communication. There's no issue about the communication at that point.

We're seeing this all kind of mesh together. I think we have this covered right now. I think it's a little bit overly burdensome to have that type of thing written into the regulation, but I'm hearing also that you're coming up with situations where you've done inspections and -- what was it? They didn't tell the utility or tell the customer?

VICTOR HALL: It's the form of communication does not make it clear and has led to item getting lost in the cracks. Prime example is I've

supplied the bolt, the bolt wasn't what it was, and I sent the email to them and I let them know that this is my 21.21(b). I told them, hey, this wasn't the ASTM and so I'm done with my Part 21 evaluation. Meanwhile, you look at the -- it's almost a double thing because they might not even realize -- they may not even realize that they had a partial responsibility in the first place. And you're talking -- I think it's especially troublesome with sub-vendors who may not do as good a job on Part 21 as a more experienced vendor. So you're talking about issues that are getting lost because, one, they may not be recognizing their deviations, and two, they're certainly not communicating up to their suppliers that, hey, you've now got the ball.

TOM LOOMIS: If they're not communicating up, putting this into regulations isn't going to solve the problem. They need to be educated to the fact that they need to be clear in their communication and their Part 21 responsibilities. So, again, putting this into regulation, I don't think is going to help you. I think it's more, you know, we need to make sure that these people understand the rules clearly.

CHRIS EARLS: Yeah, and I think we're okay with specifying some level of detail for the communication and the guidance, you know, type document, you know. So I don't -- you know, we -- Tom's right on. We would hate to see that level of detail in a rule, but certainly in a guidance document where we want to, you know, lay out what that communication should look like. You know, it could even be, you know, a checklist or something of that nature. We would be receptive to that. Absolutely.

TOM LOOMIS: Yeah, I'm sorry. I might be missing your point here, but I kind of -- when you say that, I'm hearing all these other issues kind of

creep up. If you have a clear point of discovery, then you have a clear transition as to when we know that we own it.

CHRIS EARLS: [affirmative]

TOM LOOMIS: And it's our part, and we've clearly educated these people, then there shouldn't be an issue here. And it's not necessarily about the communication because once you tell me that there is a problem with -- you think there could be a problem with this analysis. At that point, boom, that goes into the corrective action process, and we drive solution. I know at Exelon, it goes before, you know, a committee and they look at these and then you have a whole bunch of people look at this and it's like, uh-oh. And then it raises up and escalates through management. So from a utility end user perspective, when this sort of stuff comes in and we launch this into the CAP process, it gets high visibility for us to drive. It's if a guy chooses not to understand the Part 21 and he just doesn't know whether or not it meets the ASTM standard, and he doesn't care, and he's not going to tell us, then to some degree we might be blind on that.

VICTOR HALL: And Tom, my point to Ed's thought on extended condition and, you know, I'm certainly not going to question a utility's ability to take that sort of information and do the right thing with it.

TOM LOOMIS: Yeah.

VICTOR HALL: But what we have seen plenty of is vendors pushing this information out, recognizing that they need to communicate something and not putting their finger on the Part 21 responsibility. And that's what's most worrisome for me.

TOM LOOMIS: Okay. All right, I understand --

VICTOR HALL: It's not the utility's side. It's not the utility's side. It's the communication that the vendors do to anyone. And it could be utility, but it's what they communicate and not being clear on their responsibility [unintelligible].

TOM LOOMIS: If we found a vendor did that to us, they would not be a vendor anymore. Or they may be looking -- well. Next day.

[laughter]

VICTOR HALL: And maybe what might help is we can pull up some inspection reports and point to some specifics, and that might help drive our discussion.

ROBERT LINK: I think I understand that you believe that there needs to be more formality and some specificity to what the expectation is in the rule. And I guess I don't have any great objection to that, but I do see the wording at least, and I know this isn't final wording by any means, but I think the wording at least is a straw man, has a greater amount of specificity than I would expect necessary in a rule. Obviously, you know, you need to have basic information and the nature and deviation, for instance, in roman numeral IV, Nature and Deviation or failure to comply. You know, if you put a period after that, I'd probably be okay, but, because the vendor then, he's done that. The potential safety hazard that is created is maybe very, very difficult. So, again, it -- putting that level of specificity in a rule I think is probably not warranted to achieve what I hear you're concern. Clearly making us understand you shall report, and these are the basic information. And as Tom said, I'm confident that then that will initiate a dialogue that will get all the necessary information, you know, between the parties as necessary.

VICTOR HALL: Okay. What I think would be valuable in the next iteration of this document would be perhaps us putting some examples or maybe during our next meeting I could bring up some examples and paint the better picture of the problem, and then discuss what might be appropriate ruling, which -- because, you know, I...

TOM LOOMIS: And let's make sure that the rule is correct in what the real issue is. I mean, to put the requirement in there isn't going to automatically drive compliance. If you got people that are uneducated and we're not doing a good job at training, it's not, you know -- so that's why in some respects, you can rule make, and we can rule make and rule make. But unless you drive the compliance, you know, and make sure that the vendor knows about this, we're solving nothing.

VICTOR HALL: Right. Okay. Thanks.

ED BAKER: Ed Baker from Talisman International. Doing consulting for vendors and sub-vendors, I have to agree with Vic that this is a problem, and it's something we've helped a number of vendors with. With the respect to rulemaking versus guidance, Vic, I think guidance would be very helpful because then there's something that the licensees can use in educating their suppliers. It's also available then for consultants to use as a basis to say, "Here's what's acceptable to the NRC" without actually having it in the rule. So I think that would go a long way in terms of fixing the problem. But from a vendor/sub-vendor perspective, it is an issue.

TOM LOOMIS: Okay. I appreciate that. If I think that your clarity about the more guidance about this rulemaking, I'm not sure we're going to get there, but the more guidance -- and that way we can show it to these guys and

say, "Hey, this is what we expect from you. This is what we expect from your sub-vendors." And we won't go half on it.

VICTOR HALL: All right. Appreciate that.

BUTCH BURTON: Quick comments in the room? Any others? Okay.

RICH DILORENZO: Rich Dilorenzo from the Okonite Company. I just have a question regarding the notification process. Lot of times on our purchasing documents, we get instructions on who to contact and how it's supposed to be done, but we run into problems where after time goes on, that information becomes obsolete and we have difficulty in contacting the people at the licensee. Is there any sort of recommendations or guidance we could get for that?

VICTOR HALL: I would ask Tom. [laughs]

TOM LOOMIS: I'm sorry, who are you with again?

RICH DILORENZO: Okonite.

TOM LOOMIS: Okonite. What product do you provide?

RICH DILORENZO: [inaudible] power cables. Power cables.

TOM LOOMIS: Okay. And you have problems...

RICH DILORENZO: Well, a lot of times the purchasing documents we get, we get instructions to notify this particular person at this particular phone number, and then when we do have a question, we call them. They retired, they've since moved on, and I guess the people that are there don't know what we're asking for them.

VICTOR HALL: At least from the regulator standpoint, I would expect some communication to someone at the responsibility -- I'd offer some

advice on --

TOM LOOMIS: Let me ask you a question. What do you do if you can't find somebody?

RICH DILORENZO: Keep searching around until we eventually do, but it becomes -- I guess when we're on a timeframe and we want to make sure we have something handled, we are looking for a little better way to communicate to the company.

TOM LOOMIS: Yeah. I don't know that I can help you with order QA documents that maybe somebody has moved on. But you're doing the right thing. And I think that's what you guys want to see is the fact that, yeah, maybe so-and-so has moved on to be a vice president or something like that. But our expectation would be that you search and search to find somebody to alert, you know, of the --

BUTCH BURTON: Tom, make sure you speak into the mic.

TOM LOOMIS: Sorry. My presumption is that you have a job title there that's on that QA document, right?

RICH DILORENZO: Usually.

TOM LOOMIS: Okay.

RICH DILORENZO: Well, we do eventually find -- it just seems like there should be a better way to communicate some of this information. Maybe nowadays is there a way to walk to a company web page where there's a particular form we could fill out with the contact information instead of just putting it into the purchasing document itself.

TOM LOOMIS: All right. We could take that feedback and think about that. So long as that communication that's happening, that's really the

issue.

VICTOR HALL: Yeah. I think that's a good one to refer -- or for us to take back for when we do discuss guidance more in depth for the industry to have in their back pocket.

JAY SILBERG: Jay Silberg from Pillsbury. One of the reasons I think guidance is really appropriate here goes to one of the wording that you have in your proposed rule, where you would have a vendor tell the licensee that the licensee must evaluate the deviation or the sub-vendor telling the vendor that he must evaluate. That's really not the role of the vendor or the sub-vendor. And I think if you can have guidance where you tell your expectations of what information should flow up, I think that's going to solve the problem much more so than trying to tune the rule better.

VICTOR HALL: Okay. Thanks, Jay.

BUTCH BURTON: Other comments? Folks on the phone? Any comments? Hearing nothing, I don't think I picked up on anything that needs to go in the parking lot. Would you agree, Vic?

VICTOR HALL: I agree, I agree.

BUTCH BURTON: Okay. All right. Go on to number 8.

TOM LOOMIS: Did you want to go ahead on those?

VICTOR HALL: No, please go for it, Tom.

TOM LOOMIS: Yeah, you know, Vic, question for you on this one. You just want a revised LER form that adds a Part 21 check box on it? I mean, we're a little lost on what change you're trying to drive here.

VICTOR HALL: I don't want to steal -- Paul had to step away, but the issue was I guess more separating the two, separating the Part 21 process

from the LER process because, as I understand it, the LER process has been improperly credited when it did not have a report. So if an LER process was followed and no report ensued, that was improperly used to credit when a Part 21 evaluation should had been done. So I guess our thought on a solution here was to separate the evaluation piece -- if you're making a report under the LER process, then that will certainly satisfy Part 21. But if you evaluate under a different set of criteria, because I think our belief is that the criteria is -- the set a criteria for the LER process are different than the set of criteria for Part 21.

TOM LOOMIS: How so? I see them very similar to the point that -- we would see a substantial safety hazard would be -- let's take an ECCS train. If you wipe out both trains, substantial safety hazard. And so we would see that as being similar and it would meet the Part 21 litmus test. I'm just not quite sure why you would be evaluating differently on that. Because of substantial safety hazard, we would see it's the same.

VICTOR HALL: I think because the criteria in the LER process do not ask, could just create a substantial safety hazard? And certainly when you look at the dual train example is a good one. If you have the two-train system and you have a separate type of equipment, a different type of equipment in each train -- I think it's a prime example where the LER process may not get you there but the Part 21 process would.

TOM LOOMIS: Why would the Part 21 get you there?

VICTOR HALL: Because it could create a potential safety hazard.

TOM LOOMIS: You would have to have the component in both systems, then, right? Both trains. Therefore --

VICTOR HALL: If you have the two train with, say, one has a GE --

GE component, the other has a Westinghouse component. Under your LER process, if the one fails, your other train works, there's no LER report.

TOM LOOMIS: Right.

VICTOR HALL: And the Part 21 process, that's a report, because you had a critical component which would need to be reported. That could create a significant safety hazard.

TOM LOOMIS: We'll put that one in the parking lot for further discussion --

[laughter]

I don't see that at all. I don't see it at all. I think what it is we've always taken the opinion that 72 and 73 satisfied the Part 21. And it's like it's worked beautifully for us because -- and I can't think of any place where it's really failed. Now if you supply us a part and we only have it in one spot and it only affects one train and it's a redundant train, and that other redundant train, it's all the safety performance. It's an intended function. We wouldn't clip the Part 21 on that. It just wouldn't meet the litmus test. Because, again, you had two trains. The other one would survive. We'll probably need to dig into this a little bit further as to what the issue is.

VICTOR HALL: I know Paul had a meeting specifically on this topic probably about a year ago, and I think it just went through at length. So we can probably point to some of that, what came out of that. But --

TOM LOOMIS: We just want to eliminate -- we like the idea of 72/73 solving the Part 21 issue. Well, not solving, but, you know, meeting that litmus test because you find out about a component that does -- how would I say this? Bottom line, we feel 72/73 satisfies Part 21. I mean, and I think it keeps

the burden under control. It keeps Part 21 where it should be. It's kind of vendor-focused. And we should probably discuss this one a little further.

VICTOR HALL: I'd argue that the criteria differ and it's probably something that we need to take to a separate meeting to maybe look at the criteria.

TOM LOOMIS: Yeah, let's dig into the criteria.

VICTOR HALL: So, let's slide that as a parking lot item, please in there. Yeah --

JULIE KEYS: I can't help myself.

VICTOR HALL: Wait for the mic, wait for the mic.

JULIE KEYS: Julie Keys. One quick, very quick comment on this. I was at that meeting. But my understanding of how this works is your LER -- you can report your Part 21 on your LER form. They are not -- they can be mutually exclusive, if you will. So if I have a Part 21 and I evaluate it under Part 21, I can certainly report it on my LER form. So the LER form is for reporting of Part 21, but right now if I report my Part 21 on that LER form, I'd check the "other" box. And so you do not know that I've just reported a Part 21. And that has been Paul's issue.

VICTOR HALL: I don't think that's been Paul's issue because I -- I hate to speak for him, but if a report is made, I think -- well, I'm going to say we're okay now. I think the next topic has some questions about maybe improving that. But if a report is made, no problem. It's our responsibility to recognize when information is there and us to do the right thing with that. The issue is when your report is not made. When the evaluation criteria for the LER screens something out, and then you stop, and the evaluation criteria for Part 21 have not

been met.

JULIE KEYS: I'd be interested in what examples you have of that.

VICTOR HALL: Just looking solely at Part 21 -- just from Part 21, it'll say if a report has been made to the Commission under some other means, then your reporting duties have been satisfied. That's the thought behind Part 21.

TOM LOOMIS: I think what you're driving here is you're looking for individual component failures that if you expanded to put them into multiple systems, would create a substantial safety hazard. And I think the example that you're coming up with for single train, single component -- I'm not quite sure how we would -- I don't know how we would handle that one, because quite frankly, we'd fail both of our tests. We wouldn't report that.

VICTOR HALL: Okay. It's a good one for details and --

TOM LOOMIS: I'm just wondering -- well, I won't go into the detail of thinking about how many systems have -- you know. Granted you have a lot of systems where you have different vendors supplying stuff. But generally, I don't know that we've ran into a lot of that trouble. But we're interested in the examples.

VICTOR HALL: Okay.

BUTCH BURTON: Actually, before I write anything down, let me -- anybody else in the room, comments on this? Joan's going to get you.

[laughter]

LARRY CAMPBELL: Larry Campbell, NMSS. A question for the gentleman. We were talking about the two trains. And this flows over to the fuel cycle side. If that basic component that failed would not create a substantial

safety hazard, it wouldn't be a basic component to start with, because the definition of a basic component, if it fails it would create a substantial safety hazard. This is what the fuel cycle side is struggling with. But you guys would say this is a difference, as I see. This is an observation. So if it does not create a substantial safety hazard to start with, why is it a basic component?

TOM LOOMIS: We wouldn't argue the definition of a basic component. That would never come into play on this. We would just see if it took the system out. Now, now, let me give you an example here where you'd trip it, on BWRs, high pressure coolant injection. Really, it's single train system. Anything in there -- now that's always your one component issue, so anything that heads south in that automatically, boom. You'd trip the wire. You'd trip 72/73. Now single train systems, you're fine. So it's redundant systems, I think is your concern.

VICTOR HALL: But then you're making the LER report.

TOM LOOMIS: Yeah.

VICTOR HALL: And that's fine.

TOM LOOMIS: Yeah, and then you'd get the information you need on that.

VICTOR HALL: Okay.

TOM LOOMIS: But if you want to add the box on that, it says Part 21. You want to go ahead --

CHRIS EARLS: Vic, I think your suggestion that we sit down and go through this example. I mean, I was also a part of the meeting that Julie was referring to, and that's exactly, you know, the discussion we had was, you know, our folks felt that 72/73 would capture it. And so there was discussions about

let's go through the criteria with some examples and show that it either is going capture it or doesn't. But at the end of that exercise, hopefully we would all have a better understanding of whether it actually kind of captures it or not. And right now I know our folks are struggling to think of an example where 72/73 wouldn't catch it.

VICTORH HALL: Okay. Okay, okay.

BUTCH BURTON: Let's see. Bob, did you --

ROBERT LINK: Oh, we don't have a dog in this one.

[laughter]

BUTCH BURTON: Okay, all right. Folks on the phone, any comments on this? Hearing nothing. Okay. Help me capture this correctly, under number 8. The issue is redundant training versus components, or...

VICTOR HALL: I think if we left it as use of LERs to satisfy Part 21, I think that'll get us.

BUTCH BURTON: All right. Okay, I think that's it.

TOM LOOMIS: Did you have an input on this one, Sabrina, or...

SABRINA ATACK: No, I was just going to add a comment that is a slightly different beast than the fuel cycle Part 70 definition issue, because for us we're trying to define what a basic component is. And here it's already been determined, so we would expect that once you determine it's a basic component, then a defect would be reported. So I just want to make sure that that clarification was made. Because we're in a little different part of the process than what was being discussed there.

ROBERT LINK: Yeah, but I guess I didn't kind of interpret that under 9, in terms of acceptable forms of written notification. We'd get into that

aspect.

SABRINA ATACK: Yes, we will. But there was some discussion saying okay, this is a similar issue to what's happening in fuel cycle --

ROBERT LINK: Oh, okay.

SABRINA ATACK: You know, when you would make a report. And for us, we're still determining what a basic component is.

VICTOR HALL: All right. A very closely linked item. Maybe number 9, maybe we should move onto that and keep -- discussion open if folks want to chime in on 8 or 9, let's do that. Sabrina, you want to tackle that?

SABRINA ATACK: Sure, I'll give Vic a short break. [laughs] Don't misunderstand my speaking to indicate that this is a nonreactor issue. This applies to everyone, so. [laughs] So everyone can listen closely and provide comments.

Number 9 is acceptable forms of written notification under 21.21(d)(2). As we discussed previously, if an entity has knowledge that the commission has been notified in writing of a defect or failure to comply, then a report does not have to be made under Part 21. The clarification proposed that you see on the screens would just seek to ensure that those reports made -- do trigger our acknowledgment that Part 21 is being reported -- a Part 21 report is being made in those other reports. So, say you do provide a, you know, an event report. Okay, do we know that you've found a defect in a basic component and you're notifying us of that? Maybe, maybe not. You may provide information that does or does not trigger that threshold to us.

TOM LOOMIS: Why do you need to know that? I mean, if you got a report that says you've got an issue with a 72/73, why would I need to follow it

up, or if you've just put out an information notice on a fuel rod issue, why would I have to submit you something under 21.21, because that's basically what you're saying here. If you gave me an LER -- if you put out an information notice, and I know that I have this, why would I have to write a Part 21 for that when you already know about it?

VICTOR HALL: Well, Tom, it wouldn't be writing a Part 21, it would be making sure that the information you provided in some other reporting mechanism has everything that is required in a Part 21 notification. I view this as an improvement to the process. It's making sure that all the boxes in that laundry list of items that have to be reported in a Part 21 are checked. That's all this is. There'd be no additional report. There would just be making sure that the information that Part 21 requires would be included in that other report.

TOM LOOMIS: It's just that this particular section's always been a benefit to us, and has this really caused problems? I mean, there'd been places where you haven't had the information, where it's been an issue. I'm just not sure what the nexus of all this is, where this is coming from, because, I mean this creates -- I could just see this going out of control, something fierce. An auditor comes in and says, "Okay, is this" -- you know, "we just found out about this issue. You didn't list all 12 or 13 of these items. Get the Part 21 going here." And it's like, here we go again. Hundreds of hours spent on writing these things. I mean, if you know about the issue, you pick up the phone and you call about it. And if we know that you have it via some form of writing, then if there's an issue, pick up the phone and we'll follow up with this, you know, an LER. I see it as potentially very burdensome for us.

SABRINA ATACK: That's interesting feedback. I think the staff

was expecting that this would just be of minimal burden but more benefit to the staff to ensure that we're evaluating things in the proper light to make sure we're notifying the industry or our stakeholders if there may be a generic issue. So we may receive an event report that says we had a failure of a train, you know, and we exceeded this performance requirement. Well, for us we would need to know, okay, who was the supplier, you know, what they'll -- so we can say okay, is this something that's being used at another facility, you know, evaluate the generic implications. So really the intent of this was just to make sure that we're understanding when you give us an event report or another notification that you actually had a defect in a basic component, that we need to evaluate on our end to make sure we're doing our part by communication.

TOM LOOMIS: Yeah, you would find all that in a 72/73. Maybe there's not everything -- always with 72/73s, there's going to be something you read into it, because when we send them out we think they're perfect. But when you get them, it's like, wait a minute, what's going on here? So, you know, this one I could see just going -- this is another one, misintended consequences. You have to see it from our side that this is how the burden is going to create, you know, auditors, inspectors out the wazoo coming after us to be filing report after report.

SABRINA ATACK: [affirmative]

TOM LOOMIS: Maybe it's, you know, maybe the solution on this is just better communication between you and us. If you got questions, call us. Work through your resident to talk with us, and make sure, if there's an issue with our 72/73, say something. But we always, you know, we have the codes on them. We've put the suppliers in there so that you guys can react to that.

CHRIS EARLS: I think, you know, as part of the discussion from the previous item, you know, we can look at how well 72/73 captures it, one, from an evaluation perspective, but also from a reporting perspective. And if there is information that is not routinely provided, you know, maybe through the guidance we can specify what that it, you know, so that it is clear. But I think we need to look at what is actually being reported and compare it to what you're expecting and see if there is a gap. And if there is then, you know, maybe take care of that gap through the guidance.

TOM LOOMIS: Right.

SABRINA ATACK: Yeah, and when reports come into the NRC, you know, there are subscriber lists. So if something is triggered under, you know, 50.72/73, it may go to a different audience than if Part 21 were also checked. So it helps us internally to make sure we're receiving the information.

CHRIS EARLS: Which is I think why we originally asked the question about is this a simple fix, because I, you know, what do we mention about the box check was absolutely discussed, and we interpreted the responses being very positive from Paul and others that, yeah, that's what we wanted. We just need to be clear that it's a Part 21. And right now the form itself is not that explicit, and so it may be as simple as putting a check box on the LER form.

TOM LOOMIS: Yeah.

CHRIS EARLS: Specific to Part 21.

TOM LOOMIS: That will change for that. Put the box on, check it, call us, we'll tell you what you need.

VICTOR HALL: In all fairness, Tom, you asked if this is a problem that we'd seen, and I can't point to a -- I cannot point to a individual 72 or 73

report where we did not do do it. I think we have a very mature program here that looks at those. And we'll pick up the phone and call if it needs more information. I did view this more as a, you know, it's common sense. You would want this information. It would be an improvement. So if -- as we go through this process, we can describe how this would create a burden for industry and how it's not worth the effort, then I'm all for examining, you know, maybe doing it through guidance -- solely through guidance. But that's something that we can discuss, so...

TOM LOOMIS: I believe the box checking, if that helps you, go from there. I think we've got some enforcement issues over that as well, so, whatever works.

BILL HORIN: I'm Bill Horin with Winston & Strawn. This discussion suggests that this particular item would read out the decision back in '91 that licensees didn't have to be burdened by doing a Part 21 evaluation, if they report under Part 72/73. The example Sabrina mentioned -- I mean, that sounds like an internal staff processing issue, not a licensee responsibility. If we send in a report under 72, then it goes to the person in charge of 72A1-6. Well, they should have the responsibility to also see, well this is have a component issue that we should send it to our Part 21 people? That's not the licensee's responsibility. That was the whole intent back in '91 to try and reduce the burden of doing multiple evaluations, and if we evaluated under -- and, in fact, you quote in your regulatory guidance draft the language that was used to say, if you do the evaluation under 72/73 and report, okay, you're done with your evaluation on Part 21. So we have to make sure that we -- there was an intent to reduce burden back then, and I think this item seems as though it would recreate that

burden that we tried to avoid.

VICTOR HALL: I appreciate that, Bill. I think at a minimum we should look at the statements in consideration from '91 and be able to address all those if we do pursue this. So I appreciate that feedback.

BUTCH BURTON: Thanks, Bill.

VICTOR HALL: Jay has a comment.

ROBERT LINK: You know, again, I respect the discussion on 52.73 [spelled phonetically]. And I just want to maybe make sure I'm interpreting this right from, again, from our perspective. Obviously, we have reporting requirements under 70.50 Appendix A. I could even conceive a Part 20 report necessarily being promulgated by a defect. And my reading of this is just to add clarity that if I make a report under one or more of those, those reporting requirements, I can satisfy per the rule, existing rule, my reporting requirements by assuring that you have the right information, including that which is required by Part 21. I mean, if it's that simple, I don't think we have a real problem, but, you know, if it's more than that, then I need to know what we are missing.

JAY SILBERG: Vic, this is Jay Silberg again. The point I'd make is to look at this from the vendor perspective as well, because the vendors aren't going to know whether the prior writing makes reference to Part 21 and necessarily contains all the information required in 21.21(d)(4). You're looking at it solely from a licensee perspective, but if a vendor sees an information notice that comes out and says, hey, there's a problem with this component, they're not going to know the kind of information that you're now going to require them to report. So, look at it from a broader perspective before you make a change.

BUTCH BURTON: Okay. Other comments in the room? Folks on

the phone, any comments? Very quiet group on the phone. Okay, in terms of parking lot, I guess I'm kind of hearing almost like a 8 slash 9. All this [unintelligible], right?

VICTOR HALL: I think we can leave it as 8. I think 9, we have enough to go back and discuss our --

BUTCH BURTON: Okay, okay, sounds good.

TOM LOOMIS: Number 10 here on 10 CFR 50.55(e) redundancy, and I'm going to turn this over to my esteemed colleague, Mr. Ted Amundson. Go ahead, Ted.

TED AMUNDSON: Well, thank you, Tom. While we appreciate the opportunity to share some of our insights regarding 10 CFR 50.55(e), as you're well aware, we have not had a lot of experience with 50.55(e) in a number of years, and those of us that are now engaged in construction of new plants under Part 52, are beginning to gain that experience. And so we'd like to take that opportunity to share some of our insights, from our perspective, anyway, into 50.55 echo. And to that end, I would like to perhaps, first of all, draw your attention to your regulatory problem statement regarding 50.55(e). And so I think we can probably start with that, start on page 30 of the Draft Regulatory Basis.

VICTOR HALL: Ted, if you'd like, we can also bring it up on the projector, if you --

TED AMUNDSON: I can talk to it --

VICTOR HALL: Just want to offer it.

TED AMUNDSON: And this is probably -- we're going to deviate a little bit, perhaps, from some of our other feedback. From our perspective, I think we have an opportunity here to engage in rulemaking and engage in rulemaking,

that in our view, would enhance nuclear safety. And that rulemaking would be to eliminate 50.55 echo. From our perspective, we're not convinced that there is a continuing safety value with the regulation itself. I think if you go back and look at why the regulation was created originally in 1972 -- and you have characterized that in your preamble to this particular section. You look at -- really what we had a tie to was criterion 16 of Appendix B, and the notion that significant issues ought to be raised to the appropriate levels of management. And the original criteria hadn't -- original regulation had four criteria by which you made a report to the NRC during the construction phase. Subsequent to that, though, there's a lot of things that have happened. That's 40-some years ago, and a lot of things have happened. One of them, of course, was the advent of the section 206 of the Energy Reorganization Act, which promulgated Part 21. And as you pointed out in your rulemaking efforts of 1991, you recognize that the Part 21 satisfies our obligations for 50.55 echo under the Atomic Energy Act for at least three of the original criteria. And you retain the significant breakdown in the quality assurance program. But it would be our observation is that in today's environment, the Commission is well aware how the quality assurance problems that we're experiencing in our construction program. You have ready access to electronically in many cases to our corrective action programs, our problem identification and resolution programs. And we're not convinced that there would be additional value added in continuing to formally report significant breakdowns in the quality assurance program. Absent that, though -- and partly that's because those of us that are been trying to implement this regulation and trying to meet our obligations in beating that regulation -- are struggling with the appropriate criteria that one would report. As we also note that in the statements

of consideration for these regulations, that you do not want us to report trivial matters. And I think we're all in agreement that that is not adding value to the overall safety.

So we struggle with what is the appropriate threshold and what's the criteria which we use. However, we still are not convinced that -- or at least we don't understand. Perhaps we just need your perspective on how you would intend to use a report. If we make a report that a substantial breakdown in the quality assurance program has occurred, how do you intend to use that? Maybe that would help us inform that criteria. We certainly recognize that the -- as you alluded to in the document here -- that you have provided additional guidance in your revised enforcement manual that came out in July of last year. And that has been helpful to us. We are using that to help us inform whatever criteria we are using to determine whether or not a particular issue was reportable.

Now, we recognize that that's our perspective and you may not be able to -- you may not agree with our perspective on the need for -- the relative importance of 50.55 echo. But in any case, if you can't do that -- do something along those lines, I think we still need to work on the definition of the regulatory problem. We do have some problems from our perspective with the implementation of 50.55 echo. The first one, and the one that is our biggest problem, is the definition of "construction." 50.55 echo invokes the definitions found in 21.3. 21.3 defines "construction" or "constructing" to include fabrication and manufacture of components. The difficulty is is that there is also a definition of "construction" found in 50.10. In 50.10(a)(2)(viii) suggests that fabrication is not construction unless it occurs in the final location of the structure system or component that we're manufacturing.

Now, that on the surface may not lead to, you know, so what's the problem with that? Well, the issue is is you take Southern's example. We received an early site permit with a limited work authorization in 2009, I think, if I recall correctly. And we have some colleagues that are also in construction -- very much along the same timeline, same technology -- but did not receive their COL until last year, about a year ago. In the interim, we recognize that with a limited work authorization, although with 50.55(e) is silent on this issue, that it is a partial construction permit. And so we invoke 50.55 echo. But now we had -- so we were trying to get 50.55 echo into our procurement documents. But when our colleagues down the street, who were not yet required to put 50.55 echo into their procurement documents, were issuing purchase requisitions for structure systems and components that would be at some point installed into the plant. So now we had purchase orders out there for the same component from two different companies with different regulations. Furthermore, when we began to evaluate issues coming out -- then we began to evaluate issues that were coming out of from our vendors. And we were all well aware how to handle deviations and failures to comply. But the issue of the substantial breakdown in quality assurance program created some problems for us. We at Southern did evaluate breakdowns in the quality assurance program, one, to determine whether or not they were significant, and two, whether or not they could lead to the creation of a defect.

Therein lies the problem, in two parts. One is the purpose of a quality assurance program is to prevent and detect defects. It is difficult to see how a breakdown in the quality assurance program could literally lead to the creation of a defect. You recognize that there is, however, an attempt to report

substantial breakdowns in the quality assurance program, but we still struggle with what is the threshold for making that report.

So I think that we need to, at least in terms of definition of the regulatory problem, recognize that there are some continuing issues that need to be resolved. Now, in my view, many of those issues probably could be handled in guidance space. But I recognize also that there are certain legal ramifications. We recognize that and that, in some cases, rulemaking would be required to work that through. And so we would be supportive of issues that -- rulemaking that improve, if not eliminate, the regulation.

Now, in terms of the staff proposal to move the proposed elements of 50.55 echo into Part 21, we have some concerns with that, primarily in terms of potential -- now I'm going to use the word "unintended consequences" like my colleagues have been using. The point that -- although you probably would do as best you could to define when that element of 21.3 did apply and to whom it applied, I think it's going to lead to confusion because Part 21 and the guidance for documents for -- the guidance documents, 0302, that we use primarily for Part 21 -- makes it pretty clear that QA issues are not in scope of 21. And so now you're going to end up with a Part 21 that talks about QA issues and reporting issues but guidance document that says Part 1 is not in scope -- or QA is not in scope of Part 21 issues. So, I think there's some issues there. And I don't think just moving it into Part 21 space is the right thing to do.

VICTOR HALL: Okay. If I were to give my takeaways from that, it's that you seem in agreement that 50.55(e) would be great to get rid of. The question is what to do with the two pieces that are left over. And I think the examining the usefulness of these unique 50.55 echo items is high on our list

there. So we need to deal if we're going to do this. I think we're going to need some help, though, in determining what are the usefulness. I think on our side, only to look back at the historical 50.55(e) reports that we've received, see what we've done with them, see exactly what we did when we got them and whether they were useful. And from the industry side, I think it would be helpful to hear whether there is a usefulness. It sounds like you're saying there's not, and I tend to agree if not having looked into it very deeply about it tend to agree. So, I think we're aligned along most of the way. I just need to figure out what we're going to do with these unique requirements and then move forward.

BUTCH BURTON: Got another comment here.

FINDLAY SALTER: This is Findlay Salter, South Carolina Electric and Gas. So I'd like to reiterate one thing that I think Ted touched on, and that's the challenge in if you do -- say you identified -- some part of your QA program broke down, there's a real challenge there with the guidances out there and the regulation that's written and to getting to, could it have produced a defect. You've got a whole -- a QA program -- the rest of your criteria of your QA program. You make a lot of assumptions that a lot of things are working, and the way I see it, and we've been looking at this and -- then multiple people could look at it different ways. And obviously Part 21 has that same problem, but I think there is a lot of assumptions and a lot of hypotheticals that go into taking one part of your program as being broken or deficient and then translating that into a defect in the plant. So I think that's just something I wanted to echo, that we're having a major challenge with defining from an industry perspective, and that the level of effort that that takes might not necessarily add value to the NRC's process, and I would also be interested in hearing back from you all, what you

would use those reports for.

VICTOR HALL: Thanks. Makes me think of my flowchart in my head. And 50.55(e) is really, is coming from the side, right? Because in Part 21, you start with the deviation and you go down the path to determine whether that could create a defect. What 50.55(e) does is introduce this hypothetical QA breakdown piece, which circumvents the deviation. And so I think it's a fair question to ask if you had a breakdown in QA program, where QA -- call it what you want. Wouldn't that lead to a deviation would you -- get you down the path anyway. And I think that's a very reasonable question and one that, if we agree that that's true, then, there's no reason to report QA breakdowns, I think. So I think that's something we need to take a hard look at and then come to a solution to.

KERRI KAVANAGH: Hi, this is Kerri Kavanagh. I'm the chief of the quality assurance branch of NRO. We're also, if I understood the way we wrote our reg basis, we're also looking at not only the licensees having a significant breakdown, but we're also looking at your suppliers because they represent the licensee as they're constructing your facility. And we have examples out there where you might -- it might be perceived that your suppliers have had significant breakdown in their quality assurance programs. That may impact you in the future. So before we consider deleting what a significant breakdown in quality, it may not be the licensee's program, but it may be your supplier's program that we need to consider.

TOM LOOMIS: But again, that would manifest itself in the deviation, though, right?

KERRI KAVANAGH: I'm sorry?

TOM LOOMIS: But again, that would manifest itself in the deviation if there was a breakdown in the QA program.

VICTOR HALL: I don't think we've answered that question yet. I think it's worth looking at, but I don't think we've answered that question yet, definitively.

TOM LOOMIS: I'm trying to think of what examples you could give us.

KERRI KAVANAGH: I would hate to start listing some of our new COL holders' suppliers, but there are examples out there where they are receiving components and material that are not meeting the technical requirements of the procurements. And that is due to the suppliers -- presumably the suppliers' inability to meet their own QA program. Just something to think about.

VICTOR HALL: I agree a hundred percent with Kerri. She's right. I work for her, so I have to agree.

[laughter]

BUTCH BURTON: Any other -- Robert, why don’t you go for it, and then we’ll go to Ed.

ROBERT LINK: Did you have one back there?

BUTCH BURTON: Oh yeah. Ed? Is it okay if -- okay.

ROBERT LINK: Obviously, not having any experience with 50.55(e), it's difficult for us to assess exactly how the incorporation of it into Part 21 is essentially proposed here, as I understand it, could affect the scope of Part 21 as it applies to fuel cycle [unintelligible]. So, again, unintended consequences -- now, Ted touched on it and, I think, in his comment -- or at least I'll comment.

If the contents, I'll say, of 50.55(e) is transposed into 21 and it is classified, categorized scoped to, you know, Part 50 licensees -- maybe we wouldn't have an issue with that, obviously. But if some of that -- and then what you're saying is if you don't have that kind of classification or scoping within the transposition of it, now you are changing the scope as it applies to us. So, again, it gets back to the scope issue and what the intended consequences are relative to taking a Part 50 requirement and putting it into a Part 21 rule that is much broader in terms of applicability.

VICTOR HALL: I don't think we have any intention of expanding the scope of 50.55 -- the unique 50.55 of your requirements to anyone. There's no reason I see to expand the scope of who it would apply to.

BUTCH BURTON: Ed.

ED BAKER: Vic, Ed Baker, Talisman. I have a couple comments. What I'm seeing is that the language inn 50.55(e) says you pass it down if applicable. And at the same time that you're passing Part 21 down, the question is is it really applicable? But licensees are getting legal advice that it's appropriate to pass it down in some cases, and they are. When you get down to the vendor level, 50.55(e) is not directly applicable. So it's only applicable through the contract. And they really struggle with what is "as applicable" mean when they go to sub-vendors? And so even if you don't eliminate it, you really need to clarify how far down it really applies.

The second point I would make is that with respect to significant breakdowns, if you choose to use that language, you really need to clarify what that is, because that is a true struggle. It's really like pornography. You don't really know what it is until you see it, and everybody has a different view. And

I've seen examples of very bad implementation of QA programs that in my mind clearly were significant breakdowns. But we're not viewed by that by the supplier or by their customer. So you really need to address that issue, and in my opinion, guidance by the best way to do that. But there are some real issues out there. And because it's not defined, companies go into lengthy -- you think Part 21 evaluations go on a long time. Evaluations of significant breakdowns can go on even longer because it's less clear. So if the NRC really wants to know about that, you really need to define what it is you're looking to find.

BUTCH BURTON: Thanks, Ed. Good point, Ed. Other comments in the room? Anybody? Folks on the phone?

SID BERNSEN: Sid Bernsen. If you go back and recognize that 50.55(e) predates Part 21, and it also was written in a totally different environment where the NRC had a lot less information on what was going on in the construction of nuclear power plants. And the concern was that if the QA program wasn't functioning, one might not be able to trust the results. The circumstances today are totally different, and a breakdown in the program that doesn't affect the quality of a product is not insignificant. And of course all of us are paying much more attention to programs in the NRC has much more oversight over the construction phase. It seems to me that that breakdown concept is no longer valid in any circumstance. So if you go back and look at the history and considerations that were given when that was written, I think you'd find it's no longer necessary. And maybe something ought to be dispensed with.

BUTCH BURTON: Okay. Thank you, Sid. Anyone else on the phone? Comments?

VICTOR HALL: Anyone who wants to keep 50.55(e)? [laughs]

BUTCH BURTON: Okay. Any aspect of this you want to put in the parking lot?

VICTOR HALL: No, we're good.

BUTCH BURTON: Okay. Did you want to --

VICTOR HALL: We have the next three topics, I think will go quickly. So let's try to get through them and then we can do lunch.

BUTCH BURTON: All right.

TOM LOOMIS: Okay, item number 11 here on the evaluation, the counterfeit, fraudulent, and suspect items. We understand in other groups working on this issue right now. Not sure it really needs to be part of the rulemaking, what the other group developed their guidance on that and be done with it. I mean, how do you guys feel about that?

VICTOR HALL: There's a tie to Part 21. I think we'd like to emphasize is that deviations -- a counterfeit item is clearly a deviation that would go into its Part 21 process. But I think our intent to the rulemaking is nothing more than point to the work being done by the other folks and emphasize work and only clarify our in-guidance.

TOM LOOMIS: I think by definition, it already includes it. I just look at, again, unintended consequences. You don't know six months, eight months down the line what can be driven out of that. I'm totally -- you know, the industry believes it's a guidance issue. Right now rulemaking --

VICTOR HALL: I agree. And the last thing I would want to do is try to define CFSI in Part 21 because it's its own heavyweight issue.

TOM LOOMIS: Okay.

VICTOR HALL: Butch, you want to ask folks if any comments from

our guests here on the phone, or no? On the CFSI issue?

BUTCH BURTON: No?

VICTOR HALL: Violent agreement. I love it. All right. Twelve: can separate posting requirements. Tom, you want to.

TOM LOOMIS: Twelve. The issue here is do you want digital postings? Is that basically what we're looking at here?

VICTOR HALL: I think what would be fair is I would like to see the best way for Part 21 to be posted. Now, if that means for a company to put it on their intranet, because they've got folks that work at home, then by all means, I certainly don't want to constrict vendors to make them think that they've got to, you know, have a pushpin on Part 21 and put it in a coffee break room and it's not going to be seen anyways. So, I don't want to restrict what folks can use as the posting requirement. That certainly doesn't do guidance to explain that, look, it's really about communicating what Part 21 is in the most efficient way that you view possible. And so I think right now Part 21 could be seen to -- it's a bit of a dinosaur and could be seen to restrict the means of posting. Someone might read it and say, "I can't post it electronically because it doesn't allow me." Well, you know, I think electronic is just fine. I'm certainly not going to ding you for posting Part 21 electronically. So, I think through some guidance we could clear that up and make it clear that that's a good way to post it. And along with that, you know, we considered whether it'd be worth developing an NRC-approved poster, like the Form 3 you'll find at plants. If that's something that's useful, I don't think it would take a lot of work to have a standard NRC form that explains what Part 21 is, why it's important, and then that could be posted. So, those are our thoughts on improving posting requirements on Part 21.

TOM LOOMIS: Okay. I don't think we have any comment on that.

BUTCH BURTON: All right.

ROBERT LINK: The only comment we might have is on -- I mean, we don't have any objection with providing this, but it does challenge the enforcement issue as to what's adequate. And I would just offer that sometimes those things are overlooked when we flow down new -- or allowances as well as requirements. So some guidance, at least in the inspection modules perhaps, that the inspectors use might be warranted.

TOM LOOMIS: It'd be interesting to get an OGC reading on this as what would be considered acceptable or not in the current rule, just to see what they have to say about it.

VICTOR HALL: That's a very good point.

BUTCH BURTON: Okay. Other comments in the room?

VICTOR HALL: We used to laugh at the guy who came back with posting violations. So, I mean they just didn't add value, and you think you're taking away from an inspection report if you ding a vendor for having an out-of-date posting requirement. So I think it goes contrary to what we're trying to accomplish when we perform inspections, and that's [unintelligible].

BUTCH BURTON: Okay. Comments, folks on the phone? On posting. Hear nothing. Parking lot item, right, Vic?

VICTOR HALL: No, definitely not.

BUTCH BURTON: Okay.

VICTOR HALL: All right. Well, last one, evaluating reporting is training. And this is a very similar thought of -- this is an area for, I think, we can improve our communications through guidance in explaining or emphasizing if

you're working on Part 21 procurement manager, and Part 21 is part of your job, that you should be adequately trained. That's just common sense, something, I think, we could emphasize in guidance. Certainly not some area we thought that rule language change would be necessary. So, that was one thought of improving guidance for industry.

TOM LOOMIS: We concur. Can't argue with that.

BUTCH BURTON: Okay. Other comments on this? On training? Here or on the phone? Oh, Ed. Okay.

ED BAKER: Ed Baker. Actually, my comment isn't on training. Did we skip number 7? Because I had a comment on 7 and I don't know that we talked about that.

VICTOR HALL: We're going to take it all from the top. Start number 1.

[laughter]

BUTCH BURTON: We talked about it.

VICTOR HALL: Ed, we talked about it. I think we talked about some examples possibly helping illustrate the problem.

ED BAKER: Okay, my comment was on the bottom of page 23. You’re striking services associated basic components as a proposed change.

VICTOR HALL: Yeah, I'd call it administrative change. I mean, a basic component includes a service. So service is already included in it.

ED BAKER: It was in the definition. You're not changing the definition. You're just striking superfluous language.

VICTOR AHLL: Exactly.

ED BAKER: Okay. As long as OGC agrees it's superfluous.

VICTOR HALL: Hopefully they'll agree with it. We'll see. [laughs]

BUTCH BURTON: Let's see. Back to 13. Training comments. Folks on the phone. Anything? Okay. Well, I don't see -- no [inaudible]. Okay, want to break for lunch?

VICTOR HALL: Yeah, let's break for lunch.

BUTCH BURTON: All right. I have been told off line that the commercial grade dedication issues will probably go through hopefully -- no, not sure? I'm trying to give them a full lunch time. Okay. It's quarter after 12:00. Can we give them a full hour? Okay. So let's reconvene about quarter after 1:00, and we'll pick up with commercial grade dedication. Okay. Thanks, everybody.

[break]

JOAN OLMSTEAD: Hi, I'd like to welcome everybody back and I think we're ready to continue our next set of discussion topics which will be commercial-grade dedication. Vic will lead us in the discussions again.

VICTOR HALL: Thanks, Joan. If the afternoon goes as well as this morning then I'll be very pleased. I really appreciate all the feedback and I think we're -- we've got a lot of good stuff to work off of. So let's keep up the momentum. Only four hours to go. [laughs]

All right, so let's begin to item A. And -- excuse me. This is lack of regulatory guidance. I guess in the first -- in the first area, evaluating and reporting, we literally have no guidance. There's nothing out there. For dedication, the story's not as simple. We do have some guidance; in fact, we endorsed EPRI 5652 through a generic letter which -- it's not the best way to endorse guidance but it's what we did back in the -- back in the day, at least on

that one example.

And it's served us well. One of the early comments I got -- and I don't know if John Adkins is on the line from NQA, or I didn't see him here today -- but he had a fantastic group of comments he sent to me which I thought were very useful, and I wanted to just call him out because I thought they were really worthwhile. And he pointed to, I guess, the fact that we really didn't highlight NQA-1 a whole lot in this document. We touch on it in maybe several places where it's useful -- where we call it out, and what we've endorsed it. But we don't put a whole lot of emphasis on that and I think that's the reason -- is because NQA-1 is something that we will want to reemphasize when we do come out this reg guide. So John, I appreciate the comments, and I think it's something I'll certainly keep in mind when we develop our reg guides -- or reg guide for dedication, but I just wanted to, I guess, bring that up ahead of time in case he doesn't chime in on the phone because I thought it was a good -- a good comment. And with that, I'll pass it to Marc and I appreciate your feedback, Marc, on what you thought of the first topic.

MARC TANNENBAUM: Okay, well, first I'd like to thank the staff at NEI for the opportunity to share our thoughts with you and some of our perspectives. So I guess we agree that -- not that there's a complete lack of regulatory guidance, but it is -- it's out there; it's just in different places --

VICTOR HALL: Right.

MARC TANNENBAUM: -- because things have evolved over time. But -- so all those available, you kind of have to have some historical perspective to piece it all together, and it's challenging for some people. So we agree with developing regulatory guidance, and as Chris mentioned earlier, we've been

working on a revision to 5652 because that was 1988. And it'll also supersede the supplemental guidance, TR-102260, and of course we're okay with submitting that for endorsement.

And I guess the reason that we decided to revise our document was really because of what we saw going on in the industry -- the basic process -- thought process is the same, but we've supplemented it with a little bit more detail, so I think we've taken the -- tried to take the flow charts out of our head and put them down on the paper. And it recognizes a lot of lessons learned just over 20-plus years of implementing it. It also takes into consideration that things have evolved since that 5652 came out; it's probably time to revise it. We've learned a lot and the target audience is a little bit broader. You know, it was originally kind of a last resort for utilities to buy spare parts, and now in some cases, you know, we have -- like Part 70, folks using it, and of course all kinds of suppliers using it, and sometimes there's a primary mechanism to bring a basic component to market. So we're trying to address a lot of the issues that we've seen, and I think you and Vic and Paul and Rich and Kerri and Greg and others have done a really good job of keeping us up to date with what you find and what your concerns are. So we've processed those, we focused on all those in the guidance, we check the -- your website regularly for the results of end of inspection reports. We've got people on team that kind of understand those perspectives. So we think that our guidance is going to incorporate a lot of that and be pretty close to echoing the concerns that we're aware of on your end.

VICTOR HALL: That's good. And I think this might be the -- of this entire effort -- the entire rulemaking effort, I think this is the most valuable thing to come out of it -- is this revision of 5652, and we've just started getting involved at

-- with -- out helping this develop and look at what's going in. From what I've seen so far I think it's looking good, so I think this can really be a tool that will improve nuclear safety because dedication is not been performed up to snuff so far, and so I think this could really make a big step forward.

MALE SPEAKER: Nice.

VICTOR HALL: Any thoughts or comments or criticisms since this been a bit of a love-in first? [laughs]

ROBERT LINK: I respect the comments. We agree generally with the need for improved guidance, but I want to be clear, and I believe, you know, the gentleman's reference to Part 70 licensees was -- are useful with regard to the product, not necessarily the process, and then that gets back to our earlier discussions on scope and the definition and the basic component, what have you.

MALE SPEAKER: Okay.

ROBERT LINK: That doesn't mean to say that we can't take that guidance, you know, in the EPRI document and apply it. We have that built into our dedication program for the product, but that doesn't necessarily mean we've applied it to, at least for -- I'll characterize it as the proposal on the scope as it applies to IROFS. So I'm not sure that that guidance has been tested in that context, and I would hazard to guess that's something that we need to take a serious look at. But that -- the prerequisite discussion really is on the substantial safety hazard and basic component, as I've said before. So I -- you know, I don't have any objection with improved guidance; I'm just saying that the EPRI document has probably not seen a test in the context of the process versus the product as much as we might all think.

VICTOR HALL: Do you picture developing some sort -- some form of different parallel guidance or even adding to the EPRI guidance for non-reactor facilities?

ROBERT LINK: Actually, we just made available the EPRI documents. We haven't even had a chance to consume it to evaluate whether or not we could also use it as is best case, or, you know, complement it in some way, or if it says now we really need to write a unique and separate document, so we're just too early into that -- into that assessment.

VICTOR HALL: Okay. All right, any folks from the audience -- were called in.

JOAN OLMSTEAD: Any --

BUD DANIELSON: Good afternoon, I'm Bud Danielson. I'm a vice chair right now of NQA, and I know several of you around here. I just wanted to make a couple of points. First was what's coming out in NQA-1 2012, we have the dedication guidance towards software computer programs, so we'd be, in addition to what John's comment -- John Adkins's comments were -- again, his were individual comments, not from the committee officially, so just for the record, and so are mine -- individual comments. So we have that coming out probably in the next month or so. It's supposed to be published. And then the other was just that -- and I don't know if you were thinking about this for your guidance right now, what you might ultimately call this -- but one of the areas we've been seeing fairly frequent problems in DOE -- I worked for the chief nuclear safety in DOE, by the way, so that's my regular job -- we've had some major breakdowns where our prime contractors might have a dedication program, but how that's slowed down or the awareness of whether their suppliers

and subcontractors are using dedication and how well that's being controlled -- we've had some problems there. So I would imagine since a lot of our contractors are the commercial industry contractors as well, you guys probably would or could experience the same types of problems, so some guidance in that area might be helpful. How does it -- you know, what controls should a, I guess, in your case a licensee impose on their contractors on how it's slowed down and what should be done if it's slowed down -- what sort of verifications you might want to process before they -- you allow somebody to dedicate?

Then lastly, yeah, just to reiterate, we are -- we're in the process now looking at what we need to do for the 2014 edition of NQA-1. We have a lot of projects going on but I don't think we have anything active that I can remember on -- if anybody's in the Engineering Procurement Subcommittee -- but if there's something else we need to do and if we want to get it into the next edition, 14, you know, keep that communication open with us so we can get a project approved, then started. So, that's it. Thanks.

VICTOR HALL: Thanks, Bud, and I think Rich is -- Rich McIntyre was here earlier and Paul Prescott and Kerri Kavanagh are all very actively involved with NQA-1, so as things change with the rulemaking I'm sure we'll be very actively involved to keep NQA-1 as the gold standard for quality assurance programs.

BUD DANIELSON: Okay, thanks.

JOAN OLMSTEAD: Are there any other comments from people in the audience? Any comments from people on the phone? Any issues for the parking lot? [laughs]

VICTOR HALL: No, I think that's a good start.

JOAN OLMSTEAD: Okay.

VICTOR HALL: All right. How quickly it can go downhill though. [laughs] All right, Item B, proper place for dedication. This goes back to philosophically -- what the heck is dedication doing in Part 21? And the history is fascinating, but what to do with today is really the question at hand. One of our early, kind of, pipe dreams was let's make a Part 22 on that [spelled phonetically] dedication, let's really separate it properly, let's bring it out -- I think that would just create a whole host of other problems in terms of procurement documents and how you separate a separate whole new regulation just for dedication, so I think we quickly canned that idea. But I think there's still a great value in calling out dedications separately, even if it's still in Part 21, creating a separate section. This of course would involve rule language change, call it rulemaking, and so I'm curious to hear your feedback on how that might negatively impact the industry.

MARC TANNENBAUM: So, well -- you know, I guess we kind of agree that the requirements are kind of embedded in definitions, and that's not all there is in Part 21, and so I guess as a result, the industry's put together -- you know, put together guidance and we're working on that again. So I know that our guidance will -- you know, will address requirements like the previous guidance did, I guess -- you know, updated version. And I think we can do that pretty effectively in our guidance and -- regulatory guidance.

VICTOR HALL: Okay.

MARC TANNENBAUM: It helped to add some more -- you know, just more implementation type guidance.

VICTOR HALL: Right.

CHRIS EARLS: You know, Vic, I think this is an area -- I know I've

talked to you just briefly about it -- but, you know, one of the concerns I have with going down the rulemaking path is, if nothing else, it's going to delay things. You know, Marc will go through some more about the guidance he's putting together; that's probably going to be ready to go, you know, this time next year, and, you know, if we go down a rulemaking pathway here, then we're going to blatant in implementing that guidance. And I don't think that's what any of us really want to do, but, you know, we can't produce guidance on rulemaking language that we haven't seen or haven't been finalized. So that's something I'd like you to consider when you're looking at this. You know, in the big scheme of things, is it more important to get this guidance out there, you know, the way it is and make it work with the existing wording that we have out there, or do we really need to hold off on this guidance until we can get some adjustments to the rule language? And so I just want to, you know, put that thought in your head. That kind of goes to everything we're going to -- Marc's going to talk about, and I've asked him to just really focus on the guidance, because we're firmly aligned with you on the need for the guidance obviously; the efforts are already going forward. You know, in this case, the definition for dedication is in that guidance document, you know, so there's no question on where we're headed. It's I think in the same pathway that you all are. It's just how best to get there.

VICTOR HALL: Right.

CHRIS EARLS: And like I said, I would -- I'm concerned that we're going to -- we're going to put in a two, three year delay in this by just pursuing the rulemaking.

VICTOR HALL: Right. Okay. I would hope that as we get farther along and if we do decide to pursue rulemaking, if we can provide examples sort

of like what we've done in the past and what we might envision rule language to look like, then hopefully that would put some of those fears at ease and if we can -- we'll see how the whole process is moving. So I don't picture us cutting rulemaking completely off. I think there's enough issues in here to use it for a couple things to fix. So we'll -- more for later. Any other comments from folks from here or on the phone?

All right. A whir [spelled phonetically] went down with evaluating and reporting. All right. I think it's an interesting segue into Section C, which is the definition -- which is the definition of dedication. And I think one of the big drivers on why we view a huge benefit in modifying the definition and that's -- its applicability to non-reactor facilities. So if you wanted to give [inaudible] --

SABRINA ATACK: Yeah, that's a great point, Vic. As you know, many of the definitions and the content of Part 21 has kind of been reactor focused since its inception and it hasn't really been updated to encompass the non-reactor stakeholder, so this is part of the rulemaking that we would like to pursue, is to include in the definition of dedications something that's a little more specific for non-reactors whereas now the wording says that "dedication occurs after receipt when an item is designated as a basic component." We'd like to give a little more guidance on what the expectations are, you know, you're identifying critical characteristics and doing verifications to make sure that those characteristics are met in the product you're dedicating. Any feedback?

ROBERT LINK: Actually, on the proposal to make it what I read as more generic, other than the leaving in the specific reference, you know, to Part 50, Appendix B still tends to focus everybody's thought process, that's expectation, which we would not obviously believe is appropriate. But I would

like to comment on page 42, just above the kind of proposed wording, on the second paragraph: call out the need for staff plans to propose a 12-month based period for implementation of new requirements following the effective date of the final rule. And then obviously the revised procedures, trainings, dedication programs consistent with the revised rule. Staff notes commercial-grade items purchased and dedicated before the implementation date of the final rule.

And again, I hate to belabor it, but this even is in my mind clear that it's recognized -- and we appreciate the recognition by the proposal that the scope by this definition is changing. In other words, it's recognized -- I'm interpreting it's recognized that, yeah, we're going to have to apply and purchase materials that we did not purchase as commercial-grade before. That being said, I will leave that discussion for future parking lot issues. I'm not sure -- I guess I can't judge an adequate grace period right now. Twelve months seems inadequate, at least at our first thought process. If essentially all IROFS are basic components, and we discussed that before, I'm clear that we would not have all the adequate processes and procedures in place in 12 months because of the amount of work and burden that represents.

SABRINA ATACK: Thanks for the comments. I think the staff really wanted to put that wording in because we have a lot of stakeholders in the non-reactor group. It's kind of a, you know -- for me, reactors is easy. Everything is straight-forward; you've got Appendix B, whereas for non-reactors you have Part 30, 40, 70, 76, we have different terminology, different QA requirements. There's a lot to consider. For us, we put the 12-month grace period and that kind of language in to recognize that, although the staff does not feel like the scope of the regulation is changing, there is the potential that our

licensees may not have been implementing Part 21 in a manner that we feel it should have been historically, because there hasn't been guidance. There hasn't been a lot of inspection activity, and we really haven't had the opportunity to gauge understanding implementation of the requirements. So we thought it was important to allow a little bit of leniency in getting into line with Part 21 if entities are not currently in line with regulation.

ROBERT LINK: Don't get me wrong, I respect your, I guess --

SABRINA ATACK: Generosity?

ROBERT LINK: -- recognition of that issue. Obviously we believe we have been implementing Part 21 since its inception. IROFS didn't even exist, you know, as terminology, until 10, 12 years ago. So it really goes back to that and I don't want to -- I don't want to belabor that. Its then or if -- and obviously we disagree in terms of the scope redefinition, which is substantial. And all I'm saying is, yeah, I believe at least one licensee, and I'm sure there are a few others who would need a little more time to be able to put a full blown commercial-grade dedication process in place for all IROFS, because we're talking for some licensees hundreds, for some licensees thousands of components. And that takes time, just the engineering work to determine the critical characteristics, which is a necessary element of a commercial-grade dedication process. And you don't do that, you know, without deliberate review and process. So -- but again, that gets back to the scoping issue.

SABRINA ATACK: So is your concern that the breadth of the parts with non-applicability [spelled phonetically] to IROFS will be a difficulty to licensees or the actual implementation of dedication requirements?

ROBERT LINK: Both.

SABRINA ATACK: Okay. Okay. I think we have another speaker.

ED BAKER: Yeah, Ed Baker from Talisman. I would also agree that 12 months is probably not enough -- excuse me -- when you consider the planning cycle for procurements for licensees going into outages, how far in advance they make their claims for procurements, how far in advance the purchase orders are issued because the language that you've used is -- the staff notes that commercial grade items purchased and dedicated before the implementation date, the dedication may not have occurred yet, but the purchase order may have been issued 18 months in advance depending on what the item is and what the lead time is with the manufacturer. And so if you consider that, you're asking them also then to have the burden of going back and revising those unless you have a longer grace period. So I think you need to consider what the actual procurement cycle is, how far in advance they would be making -- placing these purchase orders.

SABRINA ATACK: Thanks for that feedback, and I think we'll look for additional feedback from the non-reactor licensees. I know they're a different beast in terms of outages, you know, and operations. I don't think there's as much of a rigid set of, you know, schedule in terms of when they shut down and replace components, you know, or a turnover like that, but I think we definitely need to get feedback on what a proper grace period would be if we do pursue the rulemaking in this change specifically.

LARRY CAMPBELL: Yes, Larry Campbell, NMSS. We are aware that some of the non-NMSS entities have purchased items that's in the warehouse that may not even be used for quite some time. That's a good point. Ed made the point; we will address that. I just wanted to make one other point is

that even though an item -- let's say you propose a definition of substantial safety hazards and its acceptable and we work that out, if it is an IROFS, Items Relied on For Safety is the term we use, or in Part 71/72, space an item important for safety, you still have to apply your QA program requirements when you procure that item. I just want to emphasize that. So even though it's not a basic component anymore, you still have to purchase those items as equivalent safety related IROFS, or important to safety depending on which bin you fall in.

ROBERT LINK: No -- yeah, we do and we agree with you. We are committed to our management measures as we have submitted general license applications and supporting documents. So it's not that we don't, you know, purchase and control our IROFS in a quality manner; that's not the issue.

MARC TANNENBAUM: We recognize there are some challenges for the non-Part 50 licensees, particularly if they haven't had a dedication program in place, but from our perspective we agree with the proposed definition. It's already in our draft guidance. It works well with our understanding of what the requirements have been -- expectations all along. So it's there and we're good with it.

VICTOR HALL: A lot easier on the reactor side.

MARC TANNENBAUM: A lot easier on our side.

VICTOR HALL: Is this an item that, I think, is a parking lot item just for the mere fact that I think it's a -- I call it a different view of the world from the NRC and industry side and the non-reactor side, so I think this is an area where we should identify the deltas and find out where we need to be at the end of this process. For the reactor folks, I think we're already there in terms of -- if there is no delta we can move forward.

SABRINA ATACK: Yeah, I think it would be helpful for us to understand whether the concerns are targeted mostly at the implementation or the concept of the revised definition or both, and any recommendations you have for implementation or words or ideas for the definition.

JOAN OLMSTEAD: So if I'm going to characterize this for the parking lot, the definition of dedication and the issue would be, that you want to work out, is...

VICTOR HALL: One of the non-reactor --

JOAN OLMSTEAD: Difference between reactor and non-reactor facilities?

VICTOR HALL: Impact of --

SABRINA ATACK: Impact on non-reactors --

VICTOR HALL: Impact on non-reactor facilities.

JOAN OLMSTEAD: Okay. Anything else?

BUD DANIELSON: Yeah, just -- sorry, made me think of another item. We have some facilities in DOE that are -- that have two regulators, so you're -- NRC is covering, you know, a particular scope under their rules and then the rest of the nuclear safety stuff that happens outside of maybe 71 or whatever falls under 830, so I'd want you to think about that as well how, you know, what we do currently in DOE for dedication, how we use NQA-1 and our definitions and all that kind of stuff and then, you know, how they'll mesh. So, you know, if we can make it simple and, you know, not have people have two processes or variations as they go through when they're skipping from this rule to that rule that will help. There's probably not a lot of problem, but just something to look into.

JOAN OLMSTEAD: Okay, so the impact on DOE regulated facilities?

BUD DANIELSON: DOE and NRCs -- the ones that are full regulated in a sense --

JOAN OLMSTEAD: Oh, NRC --

BUD DANIELSON: Yeah. Activities and facilities, really.

JOAN OLMSTEAD: Okay.

BUD DANIELSON: Yeah, thanks.

JOAN OLMSTEAD: I'd also like to give an opportunity for people on the phone to comment.

SID BERNSEN: Sid Bernsen. Hello?

JOAN OLMSTEAD: Yes, we can hear you.

SID BERNSEN: Okay. I -- you know, my feeling is that there's a difference between the real intent of dedication in Part 21 and the way it's evolved, because in Part 21, the objective was to make sure that people recorded defects in whatever they supplied that might have an impact on safety. And the defect recording problem occurred because once the contract was completed with the supplier, there was no control over the reported defects. And so dedication was the assumption of a responsibility for reporting. We have evolved into a process for qualifying a commercial grade item and calling that dedication, which is an enlargement of the intent of dedication.

VICTOR HALL: Sid, I guess it's -- I'd say dedication is almost a necessary evil because you have to define your set of what is safety-related, what is subject to the evaluating and reporting responsibilities, and that goes back to when -- it think it was '78 or '79 when we changed Part 21 to define

dedication, to define commercial grade item, because you had to put a definition. I think the industry's original complaint was that Part 21 applies to everything in the plant, and that's when the definition of dedication came about. So --

SID BERNSEN: No -- yeah, I understand that the purpose was, that now that plants were completed and other people were procuring equipment, they needed to know what they had to go through to essentially accept a commercial grade item and put it into the process. And so the work that EPRI did at that time was certainly necessary for the industry. But it was really a tool for defining how you determine what was really important, because you couldn't go back and verify the whole component, so you needed to determine what attributes were important, and that was useful. But the real objective was to make sure that we could classify those things that needed to be reported and those attributes that needed to be reported because they had a significant impact on safety, and who was responsible for reporting them.

VICTOR HALL: I agree, and I would agree that dedication has changed. Look at the four units being built now and a lot of those components are being dedicated starting at ground zero. So I agree that dedication has changed, but I think we can still achieve a lot of clarity by doing what we're proposing, to simplify the -- simplify the definition and give a separate section to get more detail.

SID BERNSEN: It just would be nice to go back to the statement of consideration, is when Part 21 was issued and make sure we haven't gone astray in our evolution of requirements in Part 21.

VICTOR HALL: I understand. Thanks, Sid.

TOM LOOMIS: All right, Vic. I'm still hearing you're pushing for a

rule change on this. Am I gathering that right? I guess what I'm hearing is is I'm just hearing a number of opinions here from different vendors and so forth, DOE facilities and so forth. I don't know why we would ever attempt to write a new definition that's going to be a one size fits all. This is a classic example where, you know, a guidance document to what Marc has is the best way to handle it, because to come up with a one size fits all, create a new regulation, talk about unintended consequences of where this could go.

I mean, parse it out, provide the guidance of what these people need at the DOE facilities and the reactors. Much better way, much smoother way of doing it. Because if we go ahead and try to write, you know, a complete regulation that covers all these different people -- and don't expect that it won't bleed over into, say, you know, a Part 50 license. I just see a lot of problems here in the long run.

VICTOR HALL: Yeah. Well, Tom, I'd offer you to pick your poison, because I think it's -- I think it's clear as mud right now, and I think that's -- I think it's the NRC's responsibility to provide clear regulations, and that's why I'm driving this rule change on this one. It's my -- that's my philosophy behind it. All righty. We'll agree to disagree.

TOM LOOMIS: Yup.

SABRINA ATACK: I think it was in the 1995 statements of consideration for that amendment to the rule. There was a comment that it would be nice if the rule had been changed to be a little more responsive to non-reactor entities in terms of dedication requirements and guidance. So I think that's part of what we're trying to accomplish here is to pay a little more attention to that side of the NRC-regulated entities and make sure that we're adjusting those

needs in the rule in addition to the reactors.

VICTOR HALL: We have another commenter from the -- from our crowd here.

CHARLIE VAUGHAN: Hi, Charlie Vaughan with NEI. It just dawned on me when I was listening to the discussion about the potential difficulty of implementing, for example, dedication in fuel cycle facilities compared to reactors. The reactors have a very granular understanding of precisely what's important to safety at their facilities. There are many units that are pretty much the same. The units have been studied over the years, and that's extremely well known. The fuel facilities are a broader spectrum of facilities where there's not a large database of information with regard to failures and that kind of information, and so the implementation of the Part 70 requirements and the performance criteria, et cetera, took a -- I hate to use the term "gross," but I'm going to say a more gross approach to exactly which bin things fit in. In other words, we basically split things into about three bins vertically and horizontally, and that was the degree of, you know, definition that we had. And so when you start talking about what items are critical to safety or critical to the component when you're talking about buying them, it's not extremely well known, and I think that's part of what Bob Link was alluding to is, if we have to implement this kind of program in those facilities where we have a pretty substantial amount of information to gather, it's going to be relatively difficult. That doesn't mean it can't be done. It just means it's going to be difficult. So I think there is a real difference between the two kinds of facilities, and that needs to be factored in when you think about this subject of implementation and unintended consequences and things like that.

VICTOR HALL: Thank you.

JOAN OLMSTEAD: Okay, any other comments from our callers? Any other issues to add to the parking lot?

VICTOR HALL: No, let's move on to D, and the definition of "commercial-grade item." If I had to sum this one up, I would say this is fixing for our past sins. If you read some of the statements in consideration from back when dedication was created and even after that, industry requested. They said, "We would like -- we would like the definition of commercial-grade item that's much more like what is proposed here, that leaves it pretty clear that if something is not safe-related, it's a commercial-grade item."

What the NRC responded back then was, "Well, we'd like to include this caveat that certain items can't be dedicated," and we were insistent that should be placed in the definition of what a commercial-grade item is. I believe that does us a disservice today. It's just -- the current definition doesn't match with kind of a common understanding of the English language. So I think we could -- it would be a great benefit to change the definition of commercial-grade item to make it open -- everything is commercial grade -- and describe when something can be dedicated in the -- in the regulation that describes what dedication is. That's the philosophy behind it, so I hope that explains.

MARC TANNENBAUM: Yeah, from our perspective -- from our perspective, we, you know, recognize that the definition has evolved and that there's some challenges for the -- for the non-Part 50 licensees, because they went through a different definition and they've got some exclusion requests then. But we agree with the proposed definition in the -- in the draft basis. Our guidance, again, already is using that, and you know, it -- I think -- I think it worked fine for us.

VICTOR HALL: Great. Thanks, Marc.

SABRINA ATACK: Any feedback from non-reactor entities? I think this is one of the areas that hopefully everyone is happy about, in the draft regulatory basis, because we recognize that for Part 70 facilities and especially the newly licensed ones who are doing construction now or have been in construction in the past few years, that they had to come in with exemption requests to change this definition because the words don't enable them to procure a lot of things as commercial-grade items and dedicate them, so hopefully this will be beneficial.

VICTOR HALL: Great.

JOAN OLMSTEAD: Any -- oh. Over here. We have a -- someone in the audience?

ED BAKER: Ed Baker, Talisman. I had a question on the -- on the definition, and the way it's read, it says, "Commercial-grade item means a structure, system, or component or part that thereof that affects its safety function." If it's a commercial-grade item, how do you at that point define its safety function?

VICTOR HALL: Give me -- give me one second, Ed. Let me take a look. I'm wondering if that's not a typo. Because I agree, a commercial item does not have a safety function. Just bear with me for a second. I'm going to guess that when we're talking about the part thereof that affects the safety function, I think it -- I think what that meant to encompass was breaking down safety -- you're talking about a valve, that the screw itself, if that affects the safety function, so we -- I think it would be worth taking a look at this and maybe the idea of getting rid of safety function from the definition of a commercial-grade -- a

commercial-grade item would be useful. Because I think that was just meant to describe the granularity of a piece associated with a commercial-grade item, and I think that's what that meant.

ED BAKER: I understand the basis. It just -- when you read it in this particular definition, it doesn't make a lot of sense to me, because it is a commercial-grade item --

VICTOR HILL: Right.

ED BAKER: -- and you would address the safety function as part of defining the critical characteristics as part of the dedication process. Okay. Thanks.

BUTCH BURTON: Yeah, we have another comment over here.

CLYDE MORELL: My name's Clyde Morell, I'm with NMSS and Spent Fuel, and I think been around long enough, I've said that the [unintelligible] program for dedicated spare parts way back in the '70s, so that's a little while ago. And I tell you back then, well, we couldn't get enough parts for building nuclear power plants, so that's where they came up with this idea. But today, I think we need to define, as this applies to Part 50, 60, 71 and 72, and we could just amend this definition and accomplish that, and the parts that are QA program, because as Larry implied, 71/72, doesn't have the particular QA requirements that 50 does. So we can probably change the definition and accomplish the goal. My comment.

JOAN OLMSTEAD: Do we have any comments from callers on the phone? Go ahead, we have another person in the audience.

BUD DANIELSON: Hi, Bud Danielson, DOE again. I have two -- I had one question and then a comment. The first was on slide D, when we were

talking about items. What about services? You know, designs analytical services, I mean that's the first one that comes to mind if the -- if the provider's not working under NQA-1 or doesn't have, you know, in your words, a Part 50 program, is that included or not? The other is -- the comment is, when we were updating NQA-1, we had -- I had many conversations with the NRC staff about trying to, you know, get them to break out of their mold of what they need for Part 50, et cetera, and understand that other people are using it that aren't using Part 50. So we ended up with a few definitions in NQA-1 in the new version.

Tied in with that is the question that is -- been all -- creating a lot of problems maybe with the users of NQA-1, and the arguments within the committee, I'll be honest, is whether "item" includes software. And I don't know what your -- I mean, I know -- I've heard what the intentions are of the staff -- NRC staff is with regards with that, but I don't know if that's going to be clarified or could be clarified, the definition.

On the -- on the draft on slide D, the other sort of a question, I guess, more is that we're -- the way it's phrased now, I think originally it was part of more language and tied to other phrases, and that word -- and that's where the "its" -- that was one of the comments we had when we were working on NQA-1, that the word "its" safety function was out of context and you had to, you know, you had to know other parts of the rule to understand how that made sense. So I agree that's something that needs to be fixed, but I would prefer, you know, especially for the DOE facilities that there's some -- there's still some connection with the safety function. We use that terminology in our -- in our rule, and so people have to go back to their document safety analysis and say, "What is the safety function?" So if you're going to dedicate it, you start there and you build

your characteristics from that.

Then the other question I had on that sentence is, with -- where it's -- if -- it says, "that was not designed and manufactured as a basic component." We know it's being designed and manufactured as a commercial item, but it's going to be used as a basic component, so the -- that phrasing just, I don't think, fits what actually happens. It just doesn't seem to make sense to me. And yeah, so that's it. Thanks.

VICTOR HALL: And Bud, real quick, services, yes, absolutely, they're included in the same way that a service can be -- a basic component isn't going to be a service.

BUD DANIELSON: Okay.

VICTOR HALL: And I would include software in that. I think the staff's position has always been that software, services, nut or bolt, can be a commercial item, it can be dedicated, it can be a basic component. Okay. So I think we'll -- I think that we do have a different section on software. We may not get into whether it's clear whether software can be a commercial-grade item, but I think that's something that certainly if not in the -- in the rule, in the guidance documents, we would go through -- take some effort to be clear that software can be included and services as well.

BUD DANIELSON: Okay. Thanks.

VICTOR HALL: Thanks.

JOAN OLMSTEAD: Okay, if we don't have any more comments, are there any items for the parking lot for this topic? Okay. We're 15 minutes ahead of schedule.

VICTOR HALL: What?

JOAN OLMSTEAD: Yes. Surprise, surprise. So we have a choice. We can take a 15-minute break now or keep going for another 15 minutes and take the break according to our agenda at 2:15.

VICTOR HALL: Will we keep going for at least one more?

JOAN OLMSTEAD: Okay.

VICTOR HALL: All right. Let's jump ahead to E. That's going to be clarification of dedication as a safety-related activity for reactor facilities. And the motivator behind this was really, again, kind of going back to the clarifying what dedication is, recognizing that when you perform dedication, you're making something as good as Appendix B. You're doing -- under your Appendix B program, you're doing safety-related work. And I think we've seen plenty of examples during our vendor inspections when that wasn't -- that wasn't apparent to the vendors, and as a result, you know, poor quality went into the components they supplied. So this is our effort to emphasize that dedication is a safety-related activity for reactors. And that's sort of the motivator behind it.

MARC TANNENBAUM: I guess we concur that it has to be done under an appropriate quality program. We realize there's some differences for different licensees, so we know there's some challenges there, but we think that those differences can be addressed in guidance, and maybe the guidance can focus on the specific quality activities by name instead of, you know, the rule or the QA program.

VICTOR HALL: Okay, well, sounds good. This is one where, too, the definition is pretty clear that dedication is a -- is an Appendix B activity, so I mean, it's just a matter of communicating that times 10.

Comments from folks in the -- here with us or on the phone? Shall

we go for one more before break?

MALE SPEAKER: Yes.

VICTOR HALL: All right. Well, the next one might be a good one. The next one's F, dedication plans and the importance of safety function. Here the -- here again, this is driven by deficiencies that we identified during vendor inspections of not seeing adequate documentation of dedication. I would make the argument that certainly in Appendix B and the requirements there that you must -- you must document your safety-related work. So if your dedication is being a safety-related activity, you must document your dedication, and the best way to do that that we've seen is do a dedication plan that describes your process. So this is an area where we felt the best solution was to require dedication plans. I think that -- I'm looking across the table, and I'm sure Tom is not going to like that thought, but it's an area that has been, I think, a sore spot with us on vendor inspections. It's something that -- you know, something has to be done to make sure that when a vendor is making something safety-related, that they do so properly. I'll leave it to Marc and to Tom.

MARC TANNENBAUM: We agree safety function is very important part of dedication, and that's been made clear in all the regulatory guidance that is out there. As those methods evolved, in our revision, you know, it's very clear also that safety function is something you need to focus on. And documentation, as we've seen, has been a bit of an issue, so we attempt to point out at every step of the process what you need to document and make it clear that you do have to document what you're doing, although we haven't said there has to be -- you know, there's one single format for doing it, because we realize there's lots of variety in different types of dedicating entities and the products they're

dedicating, and we agree those could be captured in, you know, more detailed guidance.

VICTOR HALL: All right. Tom, you want to take a stab at this?

TOM LOOMIS: I was just going to -- I was just going to say, so by creating a regulation to require it, we expect that it's going to be better -- it's going to be done more than what it would be through the guidance that would be endorsed.

VICTOR HALL: I'd agree with that, yeah. I -- because I think -- I think because of the way the framework is set up now, especially the way dedication is buried in these evaluating requirements, I don't think it's clear to folks.

TOM LOOMIS: Okay. Would it be helpful if we made it more clear in the guidance documents?

VICTOR HALL: Well, I mean, I think that's certainly a component to it. That's certainly a component to it.

TOM LOOMIS: You know, and again, I go back to unintended consequences. We put this into a regulation, and who knows what's going to happen with it? I think you can get what you want by just making sure that, you know -- what Marc is preparing here is very crystal clear, and we fully support that, but...

VICTOR HALL: Okay. Well, this might be an area for further discussion, because I -- and I have a hard time -- it's because of the way I -- my job function, I have a hard time picturing what the unintended consequences of this one could be.

TOM LOOMIS: And therein lies the issue. Therein lies the issue. I

mean, again, we can come in here, we can have everybody in this room agreeing on what those words look like, and I can't -- I can run down a whole list of issues. I can give you regulation after regulation, 50.55a. We put all those details in there about that regulation. Everybody agrees to it. Then seven months later, we look at -- it's like, "Wait a second. That's wrong." So we're back in there and revising the regulation again. Good guidance. That's what I'm seeing as. We think we can control it better. We got issues with it that, we can change it, and I mean, that just -- that's where we go with this. That's where we're leaning.

ROBERT LINK: And I agree completely with the principle, and again, just have to add that when I -- when I read words like "the staff has begun developing," you know, "DG12-92" -- and again, a reference to the EPRI document -- we have not really been participating in that, and from a process point of view, so somehow we're going to get -- have to get engaged to assure that some of the issues and nuances that we have relative to that implementation is understood.

TOM LOOMIS: Yeah, let me give you another example. If you look at, like, 10CFR50 Appendix G and you look at option B, NEI has a great implementation document. Gives you all the details you need to know, if you have an option A, which is the old prescriptive request. Then you have option B. Option B, the endorsing NEI document, gives the licensee everything they need to know. And if there's an issue, you know, then it's like a lot of it is just described in there. Can you hope that your regulation is going to describe every nuance that you need to understand when it comes to dedication? That's -- it goes back, again, you're going to try to write a one-size-fits-all. With guidance here, we can enforce it, you know, we can change it quickly if necessary. And so

that's kind of like where we go on this.

JOAN OLMSTEAD: Do we have any other commenters in the audience? Anyone on the phone?

VICTOR HALL: Just a quick question for Robert. You mentioned the DG and the EPRI guide that they're going on. The draft guide, it's just a placeholder right now. That will be developed later. But I wanted to ask you whether you felt that your side needed to be more involved with the -- with the development of 5662 and there's something that you felt needed to be done, I guess, for this to be a simple process.

ROBERT LINK: There's a little bit of a catch-22 in the -- in the question, in my mind, because I'm still trying to reconcile what's in and what's out. If I don't know the scope of the application which is being presented, till I know that, I really can't reflect back on the implementation guidance, whether it's an EPRI document or a draft guide or whether we create an NEI document for endorsement. All of those, I think, are opportunities for us to participate and hopefully make it simple. But again, if I don't have a clear definition of what the starting point is and scope, it's hard for me to make that judgment.

JOAN OLMSTEAD: One more -- see, oh, there is somebody that wants to comment over there.

MIKE DUNKELBERGER: Mike Dunkelberger with MPR Associates. The only real concern at all I have with the plan is that I'd want to make sure that the way it was written, it would allow for the multiple methods of containing the elements of the plan, you know, because I think in some instances, you have specific procurements that need a plan written for that specific procurement, but then other types of procurements are more generic in

nature, and the elements of a plan can really be included in like, a procedural-type format. So I would just -- that would be my main concern, that it would allow some flexibility in implementing the requirement.

VICTOR HALL: And just a quick word on my vision, I guess, when we were putting this together, is -- simple is -- you know, “keep it simple, stupid,” is the way to go. So if -- we didn’t put anything down in terms of potential language, but my thought would be a documented plan would be required. And I wouldn’t want to prescribe more than that, because there are too many variations to step in the -- stepping in the tar.

ROBERT LINK: Well, just to make sure I understand where you -- I think you’re trying to tell us where your, at least, vision is, and you know, obviously I don’t have a problem with the promulgation of a plan. Is it -- would that also mean that your -- that plan would have to be submitted and approved, I mean, changes approved?

VICTOR HALL: No. Even right now, a plan -- a dedication plan is not required to be submitted and approved. That might be a good practice. Especially for some vendors, it might be a good practice. But certainly no, it’s not something I would expect to -- require to be submitted and approved.

ROBERT LINK: Thank you.

VICTOR HALL: But a documented plan, I expect -- I expect that at a minimum.

ROBERT LINK: I understand.

JOAN OLMSTEAD: All right, I’d like to give one more opportunity for the callers to comment. Do we have anything in this topic area for the parking lot?

VICTOR HALL: I don't think so. Unless you had a discussion you wanted to add now.

JOAN OLMSTEAD: All right. Guess we can move on to the next one. G, sampling requirements.

VICTOR HALL: All right, sampling requirements. The -- to me, this is -- this is a no-brainer. We don't -- the NRC does not have guidance on sampling, has not endorsed guidance on sampling, yet there's a document out there that's 95 percent of the way there, which, when we go on inspection, it's the first thing we'll ask for if there's someone there sampling, is, what are you using as your guidance? Are you using EPRI-7218? And so this, I think, would be a huge benefit for us to, as part of our reg guide, to endorse an industry guide. And I talked to Marc quite a bit about this, and I think we're really close on finally having an endorsable guide from industry.

MARC TANNENBAUM: Yeah, we realize sampling plays a vital role, because you can't use something after you've destructively tested it, and it is important to clearly justify the basis for selection of your sample plan and to use a sample plan that makes sense for the application. And we're fine with clarifying that regulatory guidance, of course, and fine with endorsing the guideline. EPRI had revised the original 7218 one time, so now it's 07218 Rev. One. Now that was in response to NRC comments, as I understand it. We're definitely open to exploring, revising that again. I would just want to make sure that we have NRC comments first so, you know, the revision is targeted correctly and we end up with something that can be endorsed.

VICTOR HALL: I'm sure we can certainly do that. Robert?

ROBERT LINK: Again, I don't have a problem with the principle. I

mean, sampling programs are appropriate and necessary. What we have found, though, in other applications where even state or NRC has endorsed or identified reference like the NC standards, when those standards have been reactor-centric, again, it becomes very, very difficult for us to make a clear transposition of that to our situation, so -- and believe me, we've had a number of elements where regulators have said, "Well, you've got to do it in accordance with this," and we said, "Well, look at the title, let alone the scoping document of that ANSI standard. It doesn't apply." It doesn't mean we don't -- we don't respect the underlying principles that are on -- in that standard, perhaps, but how you apply it does become a practical implementation challenge.

VICTOR HALL: Thanks for that. I appreciate that. Any folks from the audience that have comments on sampling requirements and dedication? Okay.

JOAN OLMSTEAD: Anyone on the phone?

VICTOR HALL: Well, we've got two left. I'm shocked here. I thought we'd be here till 8:00 p.m. tonight. Let's keep cranking.

JOAN OLMSTEAD: Yeah. Do you want to keep going? We had scheduled a 2:15 break, or do you want to keep going?

VICTOR HALL: We got two left. Let's keep cranking, and --

BUTCH BURTON: I'm seeing headshakes.

VICTOR HALL: Let's take a break.

[laughter]

JOAN OLMSTEAD: All right. Fifteen-minute break. We'll reconvene at 2:30. Thanks.

[break]

JOAN OLMSTEAD: Hi, I'd like to welcome everyone back. We're ready to start our next session and it will be H, Use of Commercial Calibration and Testing Laboratories, and, Vic, I'll let you lead the discussion.

VICTOR HALL: Thank you, Joan. All right, these last two -- these last two, both the use of ILAC and software dedication are more pointers than anything. The ILAC one is still -- it's a thorn in our side in getting some clear guidance out there, but once we do have clear guidance the idea is in our reg guides on dedication, give a pointer -- give some details on what is an acceptable way for use of calibration -- commercial calibration and testing laboratories. So, that's one where work is being done in a parallel effort, and all we're looking to do is capture that work in our guidance.

LARRY CAMPBELL: Larry Campbell, NMSS. During the break some attendees came up to me -- can you just give a quick snapshot where we are with respect -- pretty good feel for calibrations, but where we are with the review of the international testing labs. Could you just speak to that for a minute or two?

VICTOR HALL: Sure, the quick back story on this is that the NRC approved the use of commercial calibration labs domestically when we approved an Arizona Public Service request through a safety evaluation report. This was back in 2008, I believe. We've been, I guess, informally asked to look at expanding that internationally, but we have not for now. So, internationally it's off limits for use of this process for commercial calibration and testing. But the way that's progressing now is we met with Russ Bell from NEI two days ago and he -- his update is that NEI is looking at a process for evaluating the ILAC process internationally for both calibration and testing all around the world. They are

planning on sending a submittal the NRC. I believe the latest estimate is likely -- it could be at late as 2014, we're hoping it's a little earlier, and we've committed to do a six month review on that and see if everything's okay, of course, and write some generic communications. So, that could be in line with the rulemaking effort, but that's where it's at, Larry. So, it's still a ways out and still a lot of work to be done, I guess, is the bottom line on that.

MARC TANNENBAUM: I think you pretty much covered it. NEI is pursuing the proposal for expanded use of international accredited calibration and test labs. I think that's ongoing, and in our guidance we're going to, I guess, discuss whatever the most up to date correct method is that can be used, and I think there was some confusion in the letter to APS; the words audit, survey, and things like that, and we'll, you know, we'll clarify that so at least the current expectations will be included in the guidance.

VICTOR HALL: I guess I take every opportunity I have when talking about this to remind folks, and this is redundant for most folks here I hope, that you're talking about dedication, and we did ourselves a disservice when we wrote the safety evaluation report for the Arizona Public Service request because we didn't mention dedication and we were, kind of, focused on the very request itself, but we are still talking about dedication; that's why we're talking about this in the chapter for dedication. So, for the vendors out there that are looking at using the ILAC process for commercial calibration you're still talking about dedication. You have to dedicate that commercial item. Sorry for the repeat. Any questions from folks here or folks on the phone?

MIKE DUNKELBERGER: I guess my understanding -- Mike Dunkelberger, MPR Associates -- my understanding is that the alternate method

that had been laid out, if you do it correctly, it's still considered to be acceptable as far as the NRC is concerned as a dedication process. I've also heard that, you know, it is based on the ISO 17025 standard 2005 edition. If that standard were to change would the alternate method -- I've heard some say that the alternate method would no longer be an acceptable approach because it would no longer be consistent with the standard that the NRC evaluated. From your perspective, is that a fair statement or not really?

VICTOR HALL: That's a very good question, and I don't have an answer for that. Yamir Diaz-Castillo is our point man on this technical topic. Oh, hey. I got help.

RICH MCINTYRE: Part of the process -- when we move forward there will be continuous monitoring so that would always be addressed. The expectation is it's not going to be a one time and move on. The new pick will be looking at that process continually and always -- and continuous monitoring will be part of the process, so it won't be a one time.

VICTOR HALL: That was Rich McIntyre, by the way, who didn't introduce himself. Everyone knows anyway. Thanks. Any other questions from folks here or on the phone?

JOAN OLMSTEAD: Okay, it doesn't seem like we have anything for the parking lot on this. So, you can move on.

VICTOR HALL: All right, our last one is software dedication, area I. Again, this is an area where work is -- the NRC is doing work outside this rulemaking process, but if we enter through either changing a rule or writing guidance this is an area that's just begging to be lumped in with it and referenced. I think it's pretty -- it's a pretty easy choice to choose to include this,

so I look forward to any comments or thoughts or whatever. We had a comment earlier about whether software is a commercial grade item, and we took that [unintelligible] aside, so. Offer it to Mark.

MARC TANNENBAUM: Well, we recognized this issue, I guess, few years ago. EPRI worked together with other stakeholders. We had NITSL, NQA-1, DOE, and other folks, suppliers, and licensees, different types in the room, and we put together a guideline. We called it Computer Program Dedication because that's what the experts in the room said to do -- software computer program, you know, same thing -- same scope -- and that was published in June of 2011. It was submitted to NRC for endorsement and it's currently with NRC. I think they've completed their preliminary reviews, and we're working to address any questions and make it endorsable.

VICTOR HALL: Thanks. Do we have any questions from folks here or on the phone?

ROBERT LINK: I guess we don't have a question, but I, you know, we -- again, back to IROFS scope issue, there are -- there is numerous software, I guess I just say that, that we rely on in the capacity of performing IROFS functions. I'm not saying that this process is an issue, but, again, when you look at -- you have the reg guide document you're referencing NQA-1, Part 52, you're referencing ASME standards that, you know, don't apply to us. Again, I don't know what the draft guide content will be yet, so it's basically the same thing.

JOAN OLMSTEAD: Are there any other comments from people in the room or on the phone? I'm going to give you a little more time because I know that sometimes it's hard to, you know, unmute and come into the conference.

SID BERNSEN: Sid Bernsen again. The NQA-1 standard is written to cover nuclear facilities so, in effect, that does cover more than power plants.

ROBERT LINK: Yeah, this is Bob Link. I recognize that, but we are not committed to NQA-1. We may use it as guidance, but we're not committed to it.

LARRY CAMPBELL: This is Larry Campbell. I will say that we do have one unique plant under Part 70 and that's the mixed oxide fuel fabrication facility in Aiken, South Carolina. They are required to meet Appendix B. Now, Part 76 facilities, they are required to meet NQA-1. Many of the new fuel cycle facilities have committed to NQA-1. Just to clarify it, the Part 40 plants, that's a bit different, and there are some older plants, like Bob is saying, that are not committed to NQA-1, but they do have a very robust management measures program.

JOAN OLMSTEAD: Okay, I guess we can move on. It doesn't seem like we have anything for the parking lot in this topic.

VICTOR HALL: I did, I guess -- before we move on to administrative changes, as a fair question to folks -- if there are issues that you have with Part 21 that were not raised in this document I certainly would be open to hearing them. I'm not expecting folks to have them off the tip of their tongue right now, but, like I said, when we did this session with our vendor inspectors we started with what do you hate about Part 21, and I wrote down all this stuff on the wall, and we captured, I think, everything that our folks had placed up, and that was kind of an informal session. But, similarly, I would ask that question to folks here and folks listening and anyone interested in Part 21. If there are areas that

you view as deficient that are, you know, contrary to safety or contrary to doing the right thing, this is the time and the place to add them. Having said that, I think we'll jump into administrative changes.

TOM LOOMIS: Yeah, we really don't have much to say on administrative changes just based on the fact that if, you know, we went through some of them. I think what we need to do is we'll use this as -- for the next meeting that we hold we'll go through each one of these and if we view it as an issue -- an administrative issue, by all means, you know, we'd advocate changing it, but, I mean, we're all for changing administrative issues, but I think going into each individual detail right now, I don't think we want to go there. So, in our next meeting let's take each one of these administrative issues. Some of them look like they're getting combined, some of these other changes, but we can just look at each individual one to see which ones would have to be looked at and change them to understand each one.

CHRIS EARLS: But to be clear, we don't see any problems with them right now.

TOM LOOMIS: Okay.

ROBERT LINK: The -- I guess I have a couple of questions. On I, is it really -- is the deletion intentional, in other words, making it applicable to all licensees or do you want to just add 52?

VICTOR HALL: Well, the deletion is to -- the deletion is -- it's not just to add 52, it all licensees covered under the scope of Part 21.

ROBERT LINK: Okay, so it's intentional?

VICTOR HALL: It is intentional, yes.

ROBERT LINK: Okay. All right.

VICTOR HALL: And --

ROBERT LINK: And maybe there's kind of a starting point for our dialogue on substantial safety hazard, but I also note in double-I that you've added 76, and I'm not trying to speak explicitly for them, but I am aware that USEC, which is the only Part 76 plant already has a NRC-approved definition of substantial safety hazard. So, I mean, we're not sure what the necessity is to add 76 in that context since they already have one.

SABRINA ATACK: I think the purpose is just to clean up the regulation because there was an oversight that 76 wasn't included in the initial promulgation of the rule or any revision thereto. So, it's just really an administrative --

ROBERT LINK: And, again, I don't want to speak for them, but there may be an issue relative to this definition versus what they already have approved, and they need to reconcile that by some reasonable process, and, obviously, they may have a concern if that change or that difference is meaningful in substance in terms of implementation and scope.

SABRINA ATACK: And by the definition they have approved are you speaking of the generic definition as in the rule or is there any --

ROBERT LINK: They have a specific definition for their license. It's already been reviewed and approved.

SABRINA ATACK: Okay.

VICTOR HALL: I think it's worth reiterating the intent behind administrative changes was pure cleanup, not -- this was not intended to add any additional anything, really.

ROBERT LINK: Well, and that's what we would have believed, but

at least in our discussions amongst the fuel cycle facilities, USEC had brought that issue up just to make sure that that was not the intent to change the scope of their existing definition.

LARRY CAMPBELL: Larry Campbell, NMSS. I'm familiar with USEC's definition, and that's something we will need to address and reconcile. So, I'm familiar with the definition you're talking about.

ROBERT LINK: I haven't, you know -- I'm aware, generally, of the definition myself, and who knows, maybe that's the starting point for a dialogue on what an acceptable definition would be, at least for fuel cycle facilities. I can't endorse it right now because I haven't really assessed it to my plant and differences we might have but, you know, we've got to work this thing forward, and we respect that.

VICTOR HALL: We'll open up to folks here in the audience who are on the phone; if anyone has any comments on the administrative changes please chime in.

JOAN OLMSTEAD: Okay, it doesn't look like we have any other commenters, so it doesn't look like we have anything for the parking lot, so I guess we'll move to the next topic.

LARRY CAMPBELL: Larry Campbell, NMSS. You may want to put Part 76 definition of substantial safety hazard as an issue we need to follow up on.

JOAN OLMSTEAD: So, it'd be the definition of SSH. Okay. Sure.

FINDLAY SALTER: This is Findlay Salter from SCE&G. I just have a quick question on number four, the incorrect numbering on 54 and 55(e)(4). Can you just explain that real quick for us, how that will -- about what the plan is

exactly for that?

VICTOR HALL: Sure. This is, if I remember correctly, we referenced an incorrect section -- so there must have been a change in 50.55(e). At some point there was a change, so there is no (e)(10) of 50.55(e) is what it is.

KERRI KAVANAGH: Actually, let me update. This is Kerri Kavanagh. OGC is currently doing a straight rulemaking clarification on this, they're working on that right now. So, this may be taken out of this whole effort altogether. There are fixing that as we speak.

VICTOR HALL: But what it was -- I think there was a change made in another regulation that wasn't caught up by Part 21 is what happened, I believe. So, there was pointed to (e)(10), which should have been (e)(4)(v).

FINDLAY SALTER: Okay, thank you.

JOAN OLMSTEAD: Any other comments?

ROBERT LINK: Just -- your parking lot item -- I think a better reference would be chapter 4ii. And it's not 10 CFR 52; it's the addition of Part 76.

JOAN OLMSTEAD: Anything else?

VICTOR HALL: I think it would be worth opening to -- if anyone has any comments at this point because we went pretty quickly. I'm really happy with the feedback that we've received. I think this is a lot of good information to take back in Rev. 1, and this will be, I think, much improved thanks to the feedback. I did want to ask if there was any feedback criticisms from anyone on the docket as a whole before we close and adjourn?

ROBERT LINK: Chapter five we do have a comment on.

ED BAKER: Ed Baker, Talisman. Just one question, there was a

question when we started about whether you wanted written comments on the justification. So, I didn't hear an answer to that question, so I'm just going to ask for clarification.

VICTOR HALL: I would certainly appreciate, if you want to send written comments to me I'd be happy to take a look at them, but we're not gathering formal comments as part of this process, but if you want to shoot me an email with some thoughts I'd be happy to read -- as I mentioned, I've probably received about half a dozen emails from folks saying, "Hey, I can't attend the meeting, but here's some thoughts on it." I do appreciate those. Of course, I read absolutely every one, and I do take them to heart and so I do appreciate it if folks do have some things they want to send to me.

ED BAKER: Thanks.

LARRY CAMPBELL: Larry Campbell, NMSS. During the break a lot of people came up to me, and I said, "If you do provided comments or suggested texts, please provide your rationale." Give the basis for any suggested text, references, and stuff like that. And I think everyone understood that, but I just talked to maybe half a dozen people.

GEORGE TARTAL: Let me just add to that a little bit. The reason why we're -- oh, this is George Tartal. Sorry. The reason why we're asking for this kind of feedback here at this meeting is so that everybody has a chance to engage in the dialogue, everybody has a chance to hear what the others have to say and comment on it or otherwise. If we get an email from somebody then, you know, nobody else is going to see that but us, so that's why we really desire to have this kind of feedback here in this kind of meeting.

ROBERT LINK: Chapter five?

VICTOR HALL: Chapter five. Go for it.

ROBERT LINK: Backfit rule applicability. The statements made here that none of these recommendations would result in the modification or addition of systems, structures, components, or design of a facility, or design approval, manufacturing license as far as facility. I think we've been clear -- we've tried to be clear today that at least the proposal as we understand it -- and we appreciate Sabrina's improved clarity in terms of the scoping wording on page 14. We would disagree with this conclusion. In fact, I would even go on to say that as a regulatory basis document, we find it lacking in providing the regulatory basis for the position that's represented relative to -- and I know I'm paraphrasing here -- relative to the equation of performance criteria in terms of substantial safety hazard and thereby getting, by their own characterization, all IROFS as basic components. We don't see the regulatory basis for that new interpretation. During Part 70 -- new Part 70 leaves my understanding, and I'd like to go back and review the statements of consideration, but I'm unaware of any direct dialogue or discussion in terms of that type of interpretation.

SABRINA ATACK: I do want to interject that the staff has not said that all IROFS are basic components at any time and that's not the position of the staff.

ROBERT LINK: We need to talk about that because that's what we're hearing you say, Sabrina. So, either I'm not understanding it correctly or I'm missing the nuances or clarification of how -- what's the criteria on which IROFS are excluded if performance criteria is the definition of a substantial safety hazard? I mean, it's on the parking lot already, and I don't want to belabor it here, but we need to have that dialogue.

SABRINA ATACK: Okay, we can just spend a couple of minutes on it since we're running ahead of schedule, and I'm sure nobody's in a rush to get out of here.

[laughter]

The intent of the draft language we provided was -- let me simplify it but hopefully not over simplify it -- would be that all IROFS whose failure in the administrative of -- excuse me, in the absence of an administrative control would cause you to exceed the performance requirements would be a basic component, and you also have to subtract out any redundant components because of failure and one item is identical to another would be subject to the same failure, so those would both be basic components if they were the only two IROFS preventing or mitigating and accident sequence. Does that help? You have a puzzled look.

ROBERT LINK: Well, I'm going to have to -- one, I'd like to see that written down because then I need to assess that in my own understanding. I can understand the logic, and some of my colleagues will probably shoot me for this, but I can understand the logic that if I had a sole IROFS -- a sole physical IROFS hardware and its failure would result in a high consequence event I might be able to get to the point where that's a basic component because of substantial safety hazard perhaps might be initiated, but it may not, I don't know, but a high consequence event is synonymous with -- that even has to be debated and has never seen, as far as I know, a regulatory review in that context. So, yes, we understand, and you're excluding administrative IROFS in consideration for meeting performance criteria is completely a different interpretation, at least in our opinion, as how do we get to a subset of components that may be considered

for basic components.

SABRINA ATACK: And recognize this is a starting point, and this is the staff's best effort at crafting a definition that meets the guidance that's out there on what a substantial safety hazard is, what's a major reduction in the degree of projection of the public health and safety. So, this is what we put together using the knowledge and the references that we have existing, you know, the Commission's policy statement on abnormal occurrence events, you know, NUREG 0302, historical guidance documents, information notices, OIG reports, things to that effect, and this is what we came up with. We ran it past our OGC, and we've gotten comments, and, you know, this is the best product we have at this time, but we are very open to discussing it and having subsequent meetings, probably I would expect an all-day meeting focused just on this topic to hear feedback and get ideas from you and definitely get the rationale and the basis for what you think is a basic component, and then we can give you some more description on where we are coming from on the guidance we provided, and then hopefully meet somewhere in the middle for something that works for everyone.

LARRY CAMPBELL: Larry Campbell, NMSS. I agree with everything Sabrina said. This is a starting point. And I guess this question is directed at Vic. I don't know when the next -- you're probably going to address this -- when this group will meet again, but it may well be that we may need a special section -- session just to address substantial safety hazards, because I think if the industry proposes a definition for that and we can work that out, I think that will take care of a lot of this. I don't think we're ready to say a sole IROFS is the only thing that's a basic component; we're not there yet. I'm sure somewhere

in between there we probably can get there, but we're not at that point yet to say -- and I know a lot of people in here don't know what we're talking about, a sole IROFS and all that, and I apologize, but just like a lot of people in here aren't that familiar with the term "safety-related," so thank you.

VICTOR HALL: Well, I've got some good news and some bad news. The good news is I think we did a phenomenal job today, I think, going through a lot of material. So, I don't think there's a need to host a meeting tomorrow, especially -- I know a lot of key folks will not be here tomorrow. So, I'd like to cancel tomorrow's meeting unless I see any objections from folks who absolutely want to. The bad news is I do want to solicit one more time, if you have something you'd like to bring up now is the time since there will not be a tomorrow.

SID BERNSEN: Sid Bernsen again. You know, in listening to all this, my observation is as follows: We've made the process so complex that people are trying to find ways to minimize the reporting and limit it, when, in fact, it seems to me the basic objective ought to be to make people aware of defects and things that could have some effect upon safety. If we try to keep things simple we'd probably get better reporting and more information than what we've done by creating this complex structure and process. And, so, anything you can do to simplify the process and make it clear and encourage people to report, recognizing that it's not necessarily a black mark against them, it's just something that will help everybody make sure that they don't have defective components and defective engineering and so on. And I get very upset when I see how the simple concepts of 40 years ago have evolved into these highly complex processes. So, anything you guys can do to simplify things, which I think it

should be our objective, I would encourage you to consider.

CHRIS EARLS: Yeah, Vic, I want to follow up on one of the comments I made at the beginning of the commercial grade dedication. As you know, we are charging forward on the guidance development or revision in that area and to a large extent we're -- probably to a full extent -- we're trying to adopt all the issues -- or the resolution issues that we've talked about today. It's our -- right now we're thinking that guidance is going to be ready for submittal maybe this time next year or sometime early next year and so -- and I don't know that you'll be able to answer this question, but our intent is to get that guidance endorsed, but I have a question now, if we feel that rulemaking is absolutely needed then I don't know that it makes sense for us to submit a document that uses those definitions and submit that for endorsement. I don't know that you can endorse it. And, so, I don't know if you've looked at -- considered that, but that's something we would like to talk a little bit more about because that may influence how we go forward with this. You know, one option may be that we submit it for endorsement and see what happens. The other option may be that we just set that guidance on the shelf until the rule gets done, at which point, you know, it could be presumably endorsed. And, again, you know, as I mentioned before, I don't think that's the preferable option. But if you can't endorse the guidance as it's written then we're in a bit of a dilemma.

VICTOR HALL: There also could be a third option, and I recognize the work that Marc's done on revised guidance, and I think it's tremendous. There -- once again, brainstorming -- there could be options present revised guidance to us for review as the rulemaking process is proceeding, and if we still need to change things then re-revise the guidance again. It's a possibility.

CHRIS EARLS: Yeah, that's one of the things we want to avoid. Okay? So, we do not want to, you know, have the plants go out there and change a bunch of procedures to meet the new guidance and then a year and a half later, two years down the road say, "We were just kidding. It's really this, and now you have to go through that." That's exactly what we're trying to avoid, you know, and we're trying -- we want to do the most efficient approach, you know, from a resource perspective. Changing procedures at a site is a big deal, and asking them to do it twice is not a good plan. So, that's why we would like to avoid that option. I do recognize that's an option out there.

VICTOR HALL: Okay.

BUTCH BURTON: All right, Vic's going to adjourn the meeting, but before he does that I just wanted to, one more time, emphasize folks to sign in, make sure that we have you on the record. For the folks on the phone -- or who are leaving -- for those of you who still need to make us aware of your participation, on the announcement we have George Tartal's contact information, and you can get on the record through George. Also, wanted to emphasize the feedback forms. Please take one, fill it out, leave it with us or send it in a little bit later. If -- folks on the phone -- if you need one you can give me a call, and I can get you one. Again, my name is Butch Burton. You can reach me at area code 301-415-6332. Did you have anything final you wanted to say before we turn it back to Vic?

FEMALE SPEAKER: No.

BUTCH BURTON: Okay. So, back to you Vic for close.

VICTOR HALL: Thanks Butch and thanks for facilitating today to both you and Joan. I really appreciated the help. I know these are long

meetings and not easy to sit through all the time. I just want to again say thanks to the folks here at the table, the folks who called in, the folks who came in despite the poor weather today. I think we've got a parking lot which will really help us focus on the areas that need some attention. Chris, it's not on the parking lot, but my boss is sitting here and her boss was here earlier, and I'm sure they heard your comments about what to do regarding --

BUTCH BURTON: She's here.

VICTOR HALL: Oh, she showed up. But your comment regarding whether -- if industry submits 5652 in the next year whether it's worth pursuing rulemaking, so, we'll certainly take that under consideration and call it a parking lot item for us. I just want to thank everyone and, again, for your participation. I'm kind of floored by the amount of folks that have emailed and called and shown support for this effort and shown interest in it, so, thank you.

FEMALE SPEAKER: Should I go through the parking lot and make sure it's [inaudible]?

CHRIS EARLS: One thing I was going to mention about the parking lot issues, we think that it probably makes sense to put them in groupings and have the right folks attend, you know, maybe not such a large group, but -- so, we know we have a lot of issues that need to be talked about in the other areas, so it would make sense that we get the right people from those communities to get with your folks and then, you know, some of the other areas, you know, maybe doing separate meetings so that we can try to attack those instead of trying to do them all in one meeting. So, that would be the one thing I'd ask you to look at, and we'll be glad to work with you on setting that up. And I think we probably, you know -- I don't know what your timetable is for this -- and

maybe that's something you can help us with -- is there a timetable that you're working under for getting these meetings conducted and done so that you can, you know, finalize the draft basis?

VICTOR HALL: Right. I guess the challenge has been finding a room that's available to hold so many people. I think it's reasonable to try to look in the next month to try to find a day that -- at least for the first part of the discussion; so, maybe in the next month we can look to find a date that works for most people and then we'll take it from there. Do we want to do the parking lot right now? We might as well, we've got folks here.

FEMALE SPEAKER: Careful.

[unintelligible chatter]

VICTOR HALL: Okay. So, let's start with reactor versus nonreactor categories. We'll go for -- I need some more colors. All right, now about green for reactor issues? Definition of dedication. I think this is a nonreactor -- two colors, excuse me.

SABRINA ATACK: You assumed you'd be using green first.

VICTOR HALL: I did. This is all on the fly. Okay. We'll do purple for nonreactors. And the first issue definition of dedication we said impact on nonreactors. I think this is clearly a nonreactors in purple. Chapter 4(i), the addition of Part 76, clearly a nonreactor issue. Okay. The foreign suppliers question regarding quality requirements. I would think that would be -- I think reactor -- really it focuses both. It's both.

ROBERT LINK: Both.

VICTOR HALL: Yeah. Lack of clarity of basic component for nonreactors.

MALE SPEAKER: Put a star by that one.

SABRINA ATACK: Do you have a larger purple marker?

VICTOR HALL: I need a bigger purple marker just to do -- point of discovery, we did not have any items on that. I think that was an area where we discussed pretty good here. I think we had enough feedback to take back, we didn't need it as a parking lot item. So, I'm going to cross off point of discovery unless there's any objection to that.

ROBERT LINK: I don't have a problem with you crossing it off. Obviously, if you make good on your suggestion before about putting out another revised one that would give us the opportunity to react to that.

VICTOR HALL: Absolutely. Absolutely. I think it's essential the next one is giving the language of where we talk about the point of discovery. Deviation in delivery including a flow chart. This started, I think, as a reactor, but I think applies to both. I didn't think I'd be getting exercise today. And the use of LERs to satisfy Part 21. I think that's clearly a reactor issue, so. All right, we got a good split here, and I think we can form our future meetings based on what we've got here. All right. Any other questions from folks? Closing remarks?

CHRIS EARLS: I would just thank you again for letting us have the opportunity to sit down with you and talk through this, and we really look forward to following up on these additional areas, but it looks like we're heading down the right path and we have a great start on this.

VICTOR HALL: Great, thank you. And with that, this meeting's adjourned. Thanks.

[Whereupon, the proceedings were concluded]