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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON REACTOR SAFEGUARDS

(ACRS)

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DIGITAL I&C SUBCOMMITTEE

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THURSDAY

JULY 21, 2022

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The Subcommittee met via Video-Teleconference, at 9:30 a.m. EDT, Charles H. Brown, Jr., Chairman, presiding.

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VESNA B. DIMITRIJEVIC, Member

GREGORY H. HALNON, Member

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JOY L. REMPE, Member

MATTHEW W. SUNSERI, Member

ACRS CONSULTANTS:

DENNIS BLEY

MYRON HECHT

DESIGNATED FEDERAL OFFICIAL:

CHRISTINA ANTONESCU

C-O-N-T-E-N-T-S

PAGE

Opening Remarks by Chairman 4

Introductory Remarks 7

Purpose, Scope, and Regulatory Basis of DG-1402.....13

Purpose, Scope, and Technical Basis of NEI 17-06, Rev. 1.....108

Public Comments.....160

Closing Statements by Chairman.....161

P R O C E E D I N G S

9:33 a.m.

CHAIRMAN BROWN: It's 9:33, so I will go ahead and call this meeting to order. This is a meeting of the Digital I&C Subcommittee. I'm Charles Brown, Chairman of the subcommittee.

Members in attendance are Matt Sunseri, Jose March-Leuba, Vesna Dimitrijevic, Joy Rempe, Ron Ballinger, Vicki Bier; our consultants, Dennis Bley and Myron Hecht. And we may be joined later by Greg Halnon, possibly. I think I've covered everybody. I believe Dave Petti is not with us right now.

So I will continue. Christina Antonescu of the ACRS staff is the designated federal official for this meeting. Christina, I presume the court reporter is ready. I forgot to ask that before we started.

MS. ANTONESCU: Yes, he is.

CHAIRMAN BROWN: Okay. Thank you. The purpose of this meeting is for the staff to brief the subcommittee on proposed Regulatory Guide 1.250, dedication of commercial-grade digital I&C items for use in nuclear power plants, followed by a presentation by the Nuclear Energy Institute on a technical basis of NEI 17-06, Rev. 1, guidance on using IEC 61508, SIL

-- that's safety integrity level -- certification to support the acceptance of commercial-grade digital equipment for nuclear safety-related applications.

The ACRS was established by statute and is governed by the Federal Advisory Committee Act, FACA. That means the committee can only speak through published letter reports. We hold meetings to gather information to support our deliberations. Interested parties who wish to provide comments can contact our office requesting timely. That said, we set aside 15 minutes for comments from members of the public or listening to our meetings. Written comments are also welcome.

The meeting agenda for today's meeting was published on the NRC's public meeting notice website as well as the ACRS meeting website. On the agenda for this meeting is -- can somebody mute their phone? On the agenda for this meeting and on the ACRS meeting website are instructions as to how the public may participate.

No request for making a statement to the subcommittee has been received from the public. Due to COVID-19, we are conducting today is a virtual meeting. A transcript of the meeting is being kept and will be made available on our website.

Therefore, we request that participants in this meeting should first identify themselves and speak with sufficient clarity and volume so they can be readily heard. All presenters, please pause from time to time to allow members to ask questions. Please also indicate the slide number you are on when moving to the next slide.

We have the MS Teams phone line audio-only established for the public to listen to the meeting. Based on our experience from previous virtual and hybrid meetings, I would like to remind the speakers and presenters to speak slowly. We will take a short break after each presentation to allow time for screen sharing as well as the chairman's discretion during the longer meeting.

Lastly, please do not use any virtual meeting feature to conduct sidebar technical discussion. Rather, contact the DFO if you have any technical questions so that we might bring those to the floor. I would also like to remind everybody to please keep your phone -- your microphone muted during the meeting. And if there's any background radios or stuff, they should be turned off to prevent feedback.

We will now proceed with the meeting. And I will ask Mr. Dinesh Taneja, the Senior Electronics

Engineer of the Long-Term Operations and Modernization Branch, Division of Engineer and External Hazards, and the Office of Nuclear Reactor Regulation to share his screen with us while Mr. Eric Benner, the Director of the Division of Engineering and External Hazards and the Office of NRR will make some introductory remarks before we begin today's presentation. So, Eric?

MR. BENNER: Okay. It looks like Dinesh is sharing his slides. So thank you, Member Brown. I will say that when I took my dog out this morning, he lied down on the patio because I think he wanted to get outdoor time in before it got to hot. So that makes him smart than me, so I understand.

For the introduction, you've accurately described the project. I will say this has been a long journey. We've been working on this project for six years.

It is the last remaining open item from the original integrated action plan. Now we are still doing other infrastructure work. But I think it is important to know that we laid out a plan to modernize our infrastructure, and we've been dutifully doing that with the help of the committee. And this is the last piece of that puzzle.

It's important to note for me that there

has been commercial-grade dedication process for licensees to use components that are not provided by an Appendix B supplier. That's been in place for a while and has a lot of rigor to it. This is just a way for licensees to leverage the safety integrity level certification process in their commercial-grade dedication program.

So with that, there clearly has been digital I&C technical staff involvement in the review and endorsement of the NEI process. But just as importantly and maybe more importantly, we've had good cooperation with our colleagues in the vendor inspection branch in the Division of Regional Support that oversee commercial-grade dedication processes in their entirety. So they were instrumental in ensuring that everything we're doing in this process is at least as rigorous as what we could do in commercial-grade dedication typically.

So with that, I do want to thank all the support we've gotten from the staff in that group. But with that, I will turn it over to Dinesh who will be leading the presentation today. Thank you.

CHAIRMAN BROWN: I have a couple of questions, top level questions --

MR. BENNER: Okay.

CHAIRMAN BROWN: -- and a specific item that's going to through a little bit of a monkey wrench into us finishing this up. First, the easy question is your Reg Guide 1.64 was issued I think back in 2017. And when you look at that, that's a fairly extensive thing also in terms of the document that it references and, like you say, for commercial dedication. You say you've been working on this. But why have this document in competition with Reg Guide 1.64? Eric?

MR. BENNER: I think they're in competition. I think Greg wants to speak. So I'll let Greg lead the answer.

MR. GALLETTI: Thank you, Eric. Yes, this is Greg Galletti from the Quality Assurance Vendor Inspection Branch in NRR. Mr. Brown, just to answer the question, in fact, they are not in competition at all.

The Reg Guide 1.164 which endorses the EPRI 56.52 Rev. 1 standard is still in effect and still the appropriate way to perform commercial-grade dedication. What this Reg Guide does as Eric pointed out, it leverages the SIL process for a portion of the dedication activities that one would do using the EPRI 56.52 type of dedication process. So it doesn't replace it. It supplements that process.

CHAIRMAN BROWN: I'm really -- 1.64 doesn't reference this in any way. And I'm now trying to remember when key worded the 1.250. I did not see a whole lot of reference, if any, to 1.64. I might be wrong on that. But I certainly did not see it, so --

(Simultaneous speaking.)

DR. BLEY: I appreciated that answer. Reading through, it didn't hit me at all that that was the strong difference and purpose. And I think the staff could've done themselves and all of us who try to read it a favor by making a statement that clear right upfront in the Reg Guide.

CHAIRMAN BROWN: Yeah, right in front of the Reg Guide 1.250 in the lead in would've been useful because that thought process you just went to, what I would gather, is somebody can go exercise and do it for 1.64 and not have anything to do with this particular Reg Guide if they so desire. Is that correct?

MR. GALLETTI: Yes, that's correct. If you go back and you look at every 56.52 Revision 1, one of the methods that you would apply regarding a commercial-grade dedication of anything, whether it be digital I&C or mechanical or other types of systems,

one of the methods potentially is to do commercial-grade surveys of the suppliers themselves. What's being proposed here in the new Reg Guide and the new NEI guideline is in lieu of doing that survey, you're taking credit for the SIL certification process for that activity.

It doesn't replace dedication. It doesn't change the way dedication is done in accordance with 56.62 Revision 1. It simply provides an alternative method. Instead of doing a direct survey, you're taking credit for this.

CHAIRMAN BROWN: Okay. Secondly, we did not get a copy of the IEC document. So we are totally out in left field relative to all the information in there that is referred to or utilized as part of this overall process in the NEI document. So that's just an administrative issue.

I'm not quite sure how to address that. Our intention was obviously to have a full committee meeting as opposed to another subcommittee meeting before we write a letter on this particular Reg Guide. And I don't know how extensive that IEC document is. But I presume it's not a trivial document either based on its application.

So I'm not quite sure how we're going to

be able to handle that right now. I think that doesn't say we're not going to have the meeting. Okay. It just means there's an administrative loose end because we don't know how that applies or we have nothing to refer to in terms of what it meant as you went through the Reg Guide and the NEI document.

We have to deal with that separately. You can't solve that problem right now. The other -- oh, geez, I think I just forgot my thought process.

Oh, in my past experience, I've done a number of Reg Guides where you all have endorsed IEEE standards and/or other similar U.S. standards. And you've only endorsed the standard itself, not an EPRI document that then purports or references or goes through, explains how you're supposed to deal with the standard. Why did you not just endorse the IEC standard to start out with as opposed to EPRI 1706?

MR. TANEJA: Good morning, Charlie. This is Dinesh Taneja.

CHAIRMAN BROWN: Yeah.

MR. TANEJA: So why we did not endorse the IEC standard. So IEC Standard 61508, it's one of the standards in the suite of standards that are used for safety application of digital equipment and process industry or in robotics. So there are companion

standards that go with IEC 61508.

So we are not actually using the entirety of that standard. We are just using a piece of it. Okay? So it was not that we did not want to endorse that, but our regulatory framework right now is limiting the use of that to just verifying one of the critical characteristics that is needed to be verified as part of the commercial-grade dedication activity.

CHAIRMAN BROWN: But it doesn't have to be used. Eric already said they don't have to use the SIL approach if they don't want to.

MR. TANEJA: Exactly.

CHAIRMAN BROWN: They can stick with 1.64.

(Simultaneous speaking.)

CHAIRMAN BROWN: Let me just expand that a little bit. The document, the Reg Guide, and/or -- that wasn't clear that only part of this IEC standard was being done. That still doesn't obviate the need for us to have a copy of it so we can see what part of it is applicable.

But it wasn't real clear to us, at least from my reading the NEI document is that you're fundamentally endorsing the entire IEEE -- IEC standard. And if it's only a part of it, that should've been more clear. I'm just passing this on right now

in terms of the Reg Guide. It doesn't have say it in the NEI document. But at least the Reg Guide ought to say what part of that document is being endorsed as part of this overall process.

MR. TANEJA: Okay.

CHAIRMAN BROWN: So that --

MR. TANEJA: Point taken.

CHAIRMAN BROWN: -- would be under the reason for issuance or preamble or whatever you have. It would be a good idea to make it very clear as to what we're doing over all with the document. So just bear that in mind. Is there a way -- are you all going to be able to get us a copy of that IEC document?

MR. TANEJA: So the IEC document is not in ADAMS.

CHAIRMAN BROWN: Yeah, we looked for it. We couldn't find it.

MR. TANEJA: Right. But it is available to the staff through our subscription to the IHS. Now the logistical problem that I had was I do have copies. It's, like, ten volumes.

And it gives me a warning, don't share the document. So the ACRS staff has the rights to IHS to download that document. And I think I was talking to Mike Eudy this morning about that, that we need to work

through the logistics whether ACRS staff can download it themselves from the IHS subscription. It's available to the NRC.

CHAIRMAN BROWN: Okay. Well, Christina tried to get that, and she was unable to get it. So we need to resolve that.

MR. TANEJA: We'll work with Christina on that.

CHAIRMAN BROWN: And at the end of all the presentations, Eric and Dinesh, we need to discuss how we're going to proceed since we haven't been able to see or even look at the IEC sections that are referenced and dealt with in the NEI document. So we ought to go ahead and finish the presentations. And then we ought to discuss a process for where we go, whether we have another -- we get the document and give us a few weeks to look at it and then have another subcommittee meeting and then have a full committee meeting after that or whether we think we could cover it just in the full committee meeting. So we need to think about that. So we can talk about that through the presentation.

(Simultaneous speaking.)

MEMBER REMPE: So Charlie, so I understand --

CHAIRMAN BROWN: Is that Joy?

MEMBER REMPE: Dinesh said -- this is Joy. Dinesh said that NRC staff has access to it just like we have access to ASME standards. So all NRC employees do have access to the standard. It's just you can't download it. Right, Dinesh?

MR. TANEJA: Oh, you can download it. It basically just gives me a warning, don't share it with anybody.

MEMBER REMPE: Right. All NRC staff has access to download it, but you can't share it, right? So --

MR. TANEJA: Correct.

MEMBER REMPE: -- if that's true, I've got an NRC email. I have rights to it, correct?

MR. TANEJA: I think so. Yes, you do.

MEMBER REMPE: Okay. Thank you.

CHAIRMAN BROWN: Well, Christina was unable to get it, so --

MS. ANTONESCU: I was not able to find any IEC standards in the NRC Technical Library.

MR. TANEJA: No, it's not in the Technical Library. It's in the subscription to the IHS where we have access to the consensus standards. So we have access to all the IEC standards. We are subscribed

to get those.

CHAIRMAN BROWN: Okay. We'll work out the admin to how we can go get that. If she needs help, I presume you all will help her.

MR. TANEJA: Definitely.

(Simultaneous speaking.)

CHAIRMAN BROWN: All right. Dennis, did you --

DR. BLEY: Yeah, two quick things, one just for Christina. Derek found a way to get in there for me for a different standard. So he might be able to give you a hand with that, finding it for us. I couldn't find it.

Back to the discussion about the IEC and the parts of it that apply. The Reg Guide gives us a nice summary of what's in the IEC and what all the parts are and what it's there for. But I don't think it tells us what you just told us about what parts of it you used and why you're not directly endorsing it. And I think that would be helpful in this section. Just like the part clarifying the purpose of this compared to the purpose of -- the other one was 16 --

MR. EUDY: Reg Guide 1.164. This is Mike Eudy, Project Manager for Research.

DR. BLEY: 1.164. And if you read both

of those side by side with the front matter where you might've cleared up the purpose, you wouldn't have a clue I don't think. I didn't have a clue. Put it that way. Okay? Enough said.

CHAIRMAN BROWN: Yeah, just to amplify Dennis' comment, the Reg Guide identified the seven parts of the standard. But we never got into the fact that you're only fundamentally -- or NEI is only referencing and dealing with certain parts of that. So I mean, it just made it confusing. All right. Any other comments from you, Dennis? You and I both kind of came up with these thought processes.

DR. BLEY: I don't think so. It was just going through it. You thought you had your handle of what was going on and then, oh, and that refers to this and this refers to this, the whole daisy chain of things that why it's done that way wasn't very clear. I don't know it always has to be, but it'd be nice.

CHAIRMAN BROWN: Yeah, I guess I understand a little bit. If you'd been endorsing the entire IEC, I guess what you're saying is you would've just endorsed that as opposed to incrementally or partially endorsing it through the NEI document which explains how to use that part you're endorsing. Is that correct?

(Simultaneous speaking.)

CHAIRMAN BROWN: Or is that just confusing is my thought.

MR. TANEJA: The NEI document 17-06 explains how much of the standard they're using in there. So we basically in our regulatory position simply said that we're only endorsing the parts that are used by NEI 17-06.

DR. BLEY: Okay. We didn't get that.

MR. TANEJA: Okay. I think we can clarify that. I believe it's in our Section C. The statement that we made was that it was essentially endorsing a portion that are utilized in NEI's 17-06 guidance document.

DR. BLEY: Yeah, I didn't get that. By the time I had to take an aspirin after 1(b). I couldn't understand that one. So we'll get to that later.

MR. TANEJA: Okay.

MR. BENNER: And certainly we can talk about the clarification. I think at bottom, the reason we did this the way we did is the SIL certification is an overall quality process. And we are not endorsing all of that because it has no really place to fit in our overall regulatory scheme.

Our regulatory scheme is you get components either from an Appendix B supplier. The international community doesn't, right? They don't have really that. Some members do.

But the overall scheme is not Appendix B. Or you do commercial-grade dedication to essentially have the licensee take the responsibility that, okay, I buy this thing commercial-grade and I do the oversight to ensure it's of Appendix B quality. So the whole purpose of this was how can vendors who are getting the SIL certification, how could that certification be leveraged in licensee's commercial-grade dedication processes to have some efficiencies?

So either the NRC would've had to write a complete set of guidance for how you could use SIL certification for that. Or as was the case here, the industry developed the guidance as to how to do that. And the NRC is endorsing that industry guidance. So that's how the three things, the Reg Guide, NEI 17-06, and the SIL certification fit together. And the EPRI work was just technical work that provides in our minds some technical -- additional technical basis as to why that's sufficient for us to make a regulatory finding that if you follow this process, we have confidence that the licensee is essentially doing the right things

to say that the components are equivalent to Appendix B quality.

CHAIRMAN BROWN: Okay. One other thing to make sure as you go -- that I want to at least make sure I understood is everything seems to revolve around what is referred to as a basic component. And 1.64 in the reference document that it used, I can't remember what the specific document is. There is a -- that basic document talks about -- that's the TR-102260 -- talked about a basic document.

And it refers to a basic component. And it fundamentally talked about big stuff, pressure boundaries which is not ours, stuff that could affect safety which is reactor trip systems, safeguards, monitoring systems. But then it talks about basic component. And a component to me in my old world was a resister capacitor integrate circuit microprocessor. An assembly was a circuit card.

Where in the process -- I don't know the commercial world. I dealt with the naval nuclear world. And we built stuff, never went through this. We dealt with MIL-SPEC parts. We had specs for our equipment, and then we tested the heck out of it for qualification under our own specs.

What are they certifying when they do a

commercial item? I presume they're not commercial, approving commercial-grade item, a resister and a capacitor, or are they? Are they doing assemblies like, cabinets, circuit cards, et cetera?

MR. TANEJA: The SIL certification is performed on a digital device such as PLC, single loop controllers --

CHAIRMAN BROWN: That's an assembly, though.

MR. TANEJA: -- digital transmitters.

CHAIRMAN BROWN: That's a piece of equipment. That's like a cabinet --

MR. TANEJA: Correct.

CHAIRMAN BROWN: -- or a drawer or something like that. It's not on piece parts. It's not circuit cards.

MR. TANEJA: No, it's not on piece parts.

CHAIRMAN BROWN: Okay. So this is overall equipment final piece of hardware that you deliver and plug in and connect the stuff?

MR. TANEJA: Right. Now the definition of components is from our regulatory framework. So we call SSCs structure, systems, and components.

CHAIRMAN BROWN: Yeah.

MR. TANEJA: So components is a very

broadly used term. It could go down to a resister level component or a component used in a system. So if you are talking about a protection system and we're using a PLC and a sensor, those would be the components of a protection system. So I think our definition of a regulatory framework kind of -- we are sticking with that.

So those are the components as they are defined. And similarly, the basic component is also defined in our regulation as a component that's a relied upon to perform a circulated function. Okay? So basic components, you can either buy it from a manufacturer who has a quality program like an Appendix B program. Or the other way to do it is you can buy an off the shelf commercial product and take it through the dedication activity following the dedication -- approved dedication processes which our regulation allows for.

CHAIRMAN BROWN: But that component is effectively something that measures something, processes it, and puts out and output and does something, either monitors --

(Simultaneous speaking.)

CHAIRMAN BROWN: It's not a microprocessor chip?

MR. TANEJA: No.

CHAIRMAN BROWN: It's not a memory chip?

MR. TANEJA: No, not by itself. It is contained in a component that is being dedicated.

CHAIRMAN BROWN: Yeah, the whole assembly has been tested to meet your seismic, your environmental, your EMI, whatever other stuff you want.

MR. TANEJA: Correct.

CHAIRMAN BROWN: One of the things that you might -- when I read through as I was going through 17-06 and what they were talking about, got into PRA being used to assess the capability or the viability or the safety posture of those assemblies. And then it went on to say based on your PRA, you may want to go back and redesign or redo some things so you can reduce your risk. I'm having somewhat of a hard time accepting that particular point.

We can put that aside right now. Hopefully I won't forget it. But that's one of the items that stuck out at me when they were talking about the EPRI research. So --

MR. TANEJA: We can cover that during the NEI's presentation.

CHAIRMAN BROWN: Okay. All right. Go ahead. I'm sorry to slow things down. I just wanted

to get some clarification on these other points. I believe we've also been joined by Greg Halnon. Is that correct, Greg?

MEMBER HALNON: Yes, Charlie. Just got in. Thank you.

CHAIRMAN BROWN: Okay. Hope things are working out.

MEMBER HALNON: It's getting there.

CHAIRMAN BROWN: Okay. Go ahead, Dinesh. Thank you all, you and Eric, for your patience. And you can go on, Dinesh.

MR. TANEJA: Okay. Well, good morning, everybody. Good morning, members, Chairman Brown, and the members of the subcommittee. My name is Dinesh Taneja. I am the Senior Electronics Engineer in the ERTB branch of NRR, Division of External Hazards and Engineering.

And like Eric mentioned, we've been working on this thing for some time now. It started back in 2006, this task. And a number of people have been involved in this effort.

Primarily, we had involvement of the Inspection and Quality Assurance branch from the beginning because the commercial-grade dedication activity is essentially an inspection item. And they

have the expertise in the area of inspecting commercial-grade dedication activities. So initially, we had Jonathan Ortega working with us. Now he's decided to leave the NRC and he's with DOE now.

And we had Bernie Dittman from Office of Research who worked with me on developing the Reg Guide and getting to this state and he retired in December. So we had a number of people come in and out of this process. I think the only constant there is probably me. I started with this project from its inception, and I'm still with it. So --

DR. BLEY: Hey, Dinesh.

MR. TANEJA: Yeah.

DR. BLEY: It's Dennis Bley. The kind of sense I get from having read this and the discussion that went on earlier is that you guys who have been buried in this for some time know exactly why you're doing it. And I think you read between the lines and know things the rest of us don't. Are we the first outside group who's reading the text now? Or have you run this past other groups?

MR. TANEJA: Well, it was put out for public comment and the set of comments that we received. And we had a number of public meetings during the last

six years --

DR. BLEY: Has it changed substantially since it went out for comment?

MR. TANEJA: No.

DR. BLEY: No? Okay.

MR. TANEJA: Hasn't changed at all.

DR. BLEY: Okay. I didn't go back and look. I should've done that.

MR. TANEJA: All right. So maybe the dedication activities are well understood by the licensees because they've been doing it for the last 20, 30 years. Since the number of Appendix B vendors went down back in the early '90s and they had to rely on dedicating commercial off the shelf items. So there is a lot of experience out there in the industry on how to perform these activities. And Dennis, the reason why this task was identified was primarily that a licensee wants to buy a recorder or a PLC and it's not available from an Appendix B house.

So the replacement parts because there's an obsolescence issue. So if they go out and buy a commercial product and they are just going to buy a handful of the items, most of the manufacturers were very reluctant on allowing these licensees to come into their shop and do a commercial-grade survey which

essentially requires that you're going through their life cycle development activities, looking at their quality programs, and all these -- their design decisions and how they track notification of errors and all these kind of things. So they were having a lot of difficulty trying to perform commercial-grade surveys because there was these manufacturers, really didn't have any commercial interest in dealing with that.

DR. BLEY: That's a lot of overhead for not much revenue, isn't it?

MR. TANEJA: Exactly. So that was the primarily reason why the industry identified this task. To they are basically saying that, hey, I know what we are dealing with. This would help us. And that's where we got started with this task.

So in addition, Mike Eudy has been a great help trying to manage this Reg Guide through. And David Rahn is my colleague in my division, a great help there. And Greg Galletti and Odunayo, we just call him Ayo, so they both have been instrumental in helping us get to this stage from the Inspection and Quality Assurance branch.

And Jack Zhao provided -- from my sister branch provided kind of the peer review of our effort

moving forward. So that's the makeup of our working group. So what we want to cover in this thing is what is the scope and purpose of this Reg Guide, our Draft Guide 1402.

And I'm going to provide some background. I think we've been talking about some of this already. What is being done currently to dedicate digital equipment and how the MR. PICKERING:-3 modernization project was born and where we are with that and how the development of NEI 17-06 took place.

And then I'll cover the regulatory basis for the Reg Guide and the regulatory positions that are there in our Reg Guide and resolution of the public comments. So the primary purpose of this Reg Guide is to endorse NEI 17-06, Revision 1. And it also endorses the applicable parts of the IEC 61508.

And like we've been discussing, those parts are -- and I think the way we put it in our Reg Guide Section C is that the parts that are used in NEI 17-06, Revision 1. And the IEC 61508 standard, it is a SIL certification standard developed as a part of the suite of standards. So one example that I would give you is that from process industry, there's a companion standard that is used is IEC 61511.

So what 61511 does is gives the

requirements for designing and accepting a safety instrumented system. They call it SIS. And the SIS safety instrumented system design, they use some model of risk.

So this SIS basically first they decide what the acceptable risk is and what to design this system to -- you know. It's okay for me to design it to fail. It's okay for me to not cause basically loss of revenue.

It's okay for me to not cause loss of life, so that risk -- acceptable risk aside the SIL level. So they have four SIL levels, one, two, three, and four, four being the highest. I think SIL four basically has the least amount of risk that's acceptable.

And SIL three is predominately where they end up with because of the way the architecture of the protection systems are mitigation systems. So they're use maybe multiple division or multiple instruments. And by doing -- so the 61511 provides you with the mathematical model on how to calculate the risk reduction factor and all that.

And that is very greatly used in the process industry, pharmaceuticals, petrochemical, and all those places have been using it since I think early

2000. So it's become a pretty mature process in the industry. So the 61508 standard is strictly looking at the equipment.

It doesn't care about the application it. It just looks at equipment. And it basically says that, hey, an equipment that is designed to meet SIL 3 needs to do all these things.

It needs to have self-diagnostic features. It needs to have a failsafe design where any failure happens, we know what the output would be at that failure mode and what kind of software to use. And basically it has a set of requirements that kind of says that this thing is designed to these requirements would satisfy the SIL requirement of one, two, three, our four.

And then 61511 when they design their safe instrumented system, and their design and their calculation, they make a determination, do I need SIL 2 part would work in my system, SIL 3 part work, or SIL 4 would work? So that is, like, infrastructure work. And we looked at it, but we are not really utilizing that in our work.

(Audio interference) that go out to these certifying bodies, which are independent certifying bodies, to get their certification on their PLCs or

transmitters or whatever they are, trying to sell to the industry. And when they go out to get the certification, they open up all their design to the certifying entity, essentially a commercial-grad survey. And during the process of certification, there may be some things that the design would have to change to meet the requirements of the IEC 61508.

And that process, we kind of audited some of these activities performed by this entity called Exida in Pennsylvania. They have been doing commercial-grade -- not commercial-grade, SIL certification for some time now. And they've written a lot of books on this thing.

And so they also provide training classes on this and that. So we kind of studied that by taking the training from them and looking and observing how they perform these certification activities. So the other standard that we are endorsing as applicable to this is the ISO IEC 17065.

So that is the certifying body that's certified. It's basically validating that those are credible entities. And that credibility is basically that they meet the 17065 standards to perform some technical activities.

And in the U.S., ANSI -- which they call

themselves ANAB now -- ANSI National Accreditation Board. So they perform periodic audits of these -- what they're calling as the accredited certifying body to make sure that their accreditation is -- they following a rigorous control process of conducting their work. So it's very much like a QA program.

They have procedures. They have qualified people. And they also look at the technical part of how are they actually utilizing the IEC 61508 standard in their activities.

So that's the part of the standard that we are endorsing by this thing. And also, I think we made the attempt of describing the relationship between the Reg Guide 1.164 and EPRI TR-106439 and this guidance. So EPRI TR-106439, so a little bit of history here.

Back in early '90s, EPRI developed the 56.52 document, 56.52, which was essentially how to perform commercial-grade dedication on anything, whether it's concrete, nuts and bolts, pipe fittings or valves, and ANSI equipment and everything else. So that standard was reviewed and approved by the NRC back in the '90s. But we did that back then using probably a safety evaluation and did not really produce a Reg Guide in those days.

And subsequently, EPRI came up with this standard, EPRI TR-106439. Now what this technical report did is provide additional guidance to support dedicating digital equipment. And the one major difference was so our regulation requires us to -- in dedication to identify the critical characteristics of the item and then do verification that they meet those -- they satisfy those requirements.

So for digital items, the critical characteristics that's unique to it what they call is dependability critical characteristics and TR-106439 which is essentially saying that I don't know what you did with the -- how you got there to the end product, what standards you use, what kind of software, life cycle activities you have. So what that standard says is to go perform a commercial-grade survey of the manufacturer to verify some of these activities. And the verification of the dependability critical characteristic primarily done by doing commercial-grade surveys. So that has been used.

EPRI TR-106439 has been used by the industry which was endorsed by the NRC in late '90s, I believe, with a safety evaluation report. And industry has been using that up until currently doing the commercial-grade dedication of digital items. Any

questions?

(No response.)

MR. TANEJA: All right, we'll go to the next slide. So I think I've covered a lot of the background, TR-106439 approach. So the Reg Guide 1.64 like Greg mentioned earlier, so EPRI issued a Revision 1 to 56.52 recent.

And this time, I think the agency decided to use a Reg Guide to actually endorse that. Now if you look at that Reg Guide, it basically doesn't include endorsement of TR-106439. It just basically recognizes that it's there and already been endorsed.

So that Reg Guide for dedicating anything and everything. It lays out a framework for dedicating a commercial off the shelf item, whether it is like mechanical equipment, a valve pump, or electrical equipment or even nuts and bolts to that point. So it's just whatever you're dedicating, you take that item, you identify what the critical characteristics are, and then you go ahead and verify those critical characteristics using one of the four methods that are in our regulations.

So Method 1, for example, is special tests and inspections. So for example, if I think we were doing a bolt, we might do some type of destructive test

to look at the strengths of the material and all that kind of stuff, right? So Method 2 is commercial-grade survey of the supplier which is recommended practice which is being followed.

We're doing the digital item verification of the dependability critical characteristics. Method 3 is source verification which essentially may apply to some of these items where you're worried about the source of the material and how they came about. And Method 4 is the acceptable supplier item performance record. So again, it's part of a survey of the supplier and looking at the performance record, how they track failures and how they report failure and all that type of things. So that's the --

CHAIRMAN BROWN: Dinesh?

MR. TANEJA: Yeah?

CHAIRMAN BROWN: All that's in 1.164?

MR. TANEJA: Well, it's all in EPRI 56.52. That's endorsed by Reg Guide 1.164, yes.

CHAIRMAN BROWN: Oh, okay. I read 1.164, and I didn't see all that definition of methods in there. So you're saying it's buried -- not buried. That's the wrong term. Don't take that the wrong way. It's caught up in this --

MR. TANEJA: This is EPRI 56.52, Rev. 1.

CHAIRMAN BROWN: Yeah, it's just 56.52 in the Rev. 0 of 1.164. You're saying Rev. 1 is now out?

MR. TANEJA: No, that was endorsed by Reg Guide 1.164, Rev. 0.

CHAIRMAN BROWN: Oh, okay. Because the Rev number is not listed on the -- at least in the reason for issuance. It's probably --

(Simultaneous speaking.)

DR. BLEY: Dinesh?

MR. TANEJA: Yes?

DR. BLEY: This is Dennis. I thought that's what we were referring to is Rev. 1 to EPRI 56.62 and TR-102260 from 2014. How does that relate to the one you have on the screen, 106439 which is earlier, right?

MR. TANEJA: So 106439, like the earlier version of EPRI 56.62 predates 106439. Now --

DR. BLEY: Okay.

MR. TANEJA: So when they revised 56.52, EPRI did not feel that there was a need to revise 106439 because what that really does, it provides you with a supplemental guidance on how to do dedication of digital items. But the process that you follow is still laid out in 56.52.

DR. BLEY: Okay. I think it got it. Go

ahead.

MR. TANEJA: Right. So that's really what the relationship is between Reg Guide 1.164 and the EPRI TR-106439. So --

CHAIRMAN BROWN: Is it 56.52 that does the -- is that the glue that connects 1.164 to 106439?

MR. TANEJA: The 56.52 is the motherboard standard on how you do commercial-grade dedication in general of any commercial item. It does not get into any specifics on the distinction between is it a mechanical item, is it a cinder block, or is it a bolt or is it electrical equipment or digital equipment? It just lays out a process on how would one go about performing a commercial-grade dedication activity, right?

So the TR-106439 now gets into -- it basically gives you guidance on -- if you're doing a digital equipment, these are the things you're going to worry about and these are the things you're going to say that these are critical to me to verify, right? So one of the characteristics that 106439 uniquely identifies for this item, they call it dependability critical characteristics. And then it gives you under that what are you looking for and how do you go about verifying that the equipment meets all these critical

characteristics.

So that's really what it does. And it supplements the guidance provided in EPRI 56.52. So in a preview, 56.62, I guess we endorse it in 2016, 2017. It was recently revised. EPRI didn't feel there was any impact to 106439.

MR. GALLETTI: Dinesh, this is Greg Galletti again. If I could just add one thing to that. The revision of 56.52, which is now 56.52, Rev. 1, does have a specific section on digital systems and does, in fact, refer directly to the EPRI TR-106439 by reference. So there is that connection.

MR. TANEJA: Okay, right. But they did not feel the need to update 106439. It's still good, right, as is.

MR. GALLETTI: Yes.

DR. BLEY: This is Dennis again. Could I try and see if I've got it? There was an original 56.52 that was general for all equipment. Then we got the 106439 specializing to digital.

And then there was the revision to 56.52 that now has a section that includes digital. Therefore, that's the reason they didn't feel a need to update 106439 because it's now included in 56.52. Did I get that right?

MR. GALLETTI: Well, it's included -- again, this is Greg Galletti from the staff. It's included by reference 56.52, Revision 1. And in fact the guidance that is embodied in 106439 is still quite applicable. So I can't speak for EPRI. But I believe that the methodology, the types of information and characteristics of interest for digital systems remain the same.

DR. BLEY: Okay. And Rev. 1 of 56.52 points to 106439? I think --

MR. GALLETTI: Yes, it does, yes.

DR. BLEY: Okay.

CHAIRMAN BROWN: Only because it's in the references, though?

DR. BLEY: I said there's a second point to it.

MR. GALLETTI: There is a section. I think it's Section 11 if I'm not mistaken on digital I&C. And it's more than just references. But as part of the description under that section of 56.52, Revision 1, there is a list of pertinent regulatory and industry standards and guidance that's identified. 106439 is one of those identified references.

CHAIRMAN BROWN: Dennis, I think you and I need to go back to stone tablets and chisels.

DR. BLEY: Yeah, we might be too old for this. Okay.

CHAIRMAN BROWN: Yeah, I've lost track of the number word salad here. So all right. Do you have anymore, Dennis? Or should be go on?

DR. BLEY: No, I don't. I think I get how it all ties together. But it's -- I'm glad I'm not a new I&C guy coming up with this to sort through all of this. The people who have been around it probably have it down pretty well.

CHAIRMAN BROWN: Yep. Okay. Do you want to proceed, Dennis -- excuse me.

MR. TANEJA: Sure.

CHAIRMAN BROWN: Dinesh. I apologize for that.

MR. TANEJA: Dennis, Dinesh, yeah, close enough.

CHAIRMAN BROWN: I bit my tongue and didn't mean to do that.

MR. TANEJA: I just don't have Dennis' qualifications, that's all. Yeah, in April of 2016 is when NEI proposed a task under the DI&C Integrated Action Plan. To leverage the SIL certification performed in accordance with IEC 61508 in the commercial-grade dedication of digital equipment.

And the proposal, the way they laid out was just that and the reasoning behind was that we are having difficulty doing commercial-grade surveys of these manufacturers. They won't let us into their shop. And so we've been looking at this other industry effort which is using this framework where they are using these third parties to perform the certification activities that kind of -- it does very similar activities of what we do as recommended by TR-106439 to verify under the commercial-grade survey.

So if we can buy a piece of equipment, digital equipment, that has a SIL certification, then by virtue of that, we can say that we have basically met the requirement of performing that commercial-grade survey because this certifying body has already conducted that. And I am accepting their work on their behalf. So that was really the premise of this activity and how it was started, right?

And so what the NEI at that time basically pointed to was NEI 14-05 as the framework for developing this new guidance for digital work. So NEI 14-05 had already gone through rigorous work with the staff and it was approved. And what that does it basically allows for procuring commercial-grade lab and calibration and test services.

So we basically said that, hey, there is precedence. We can probably follow some similar path in trying to do -- can we take advantage of this work done by the industry and the non-nuclear arena for safety applications? And that's really where this thing came about. And so I think if you look at basically the title of IEC 61508, it is talking about safety-related digital equipment, essentially.

So now every industry has requirements for safety-related components. And this is the framework that the IEC worked on it. I think it started back in '90. The original revision to the standard was issued in 2000. And now I think the last revision was 2010, I believe. And --

DR. BLEY: Could I sneak in again? This is primarily for Charlie. I did some digging while Dinesh was talking. In EPRI's 56.62, Rev. 1, they did add a last chapter, Chapter 14, which is two pages long. And it in several spots sends you back to 106439. So that's how they are tied together. That's all. Sorry, Dinesh. Go ahead.

MR. TANEJA: All right. So next slide.

CHAIRMAN BROWN: One more thing just to make sure I understand. This is not detailed. The reason you didn't identify the IEC 61 -- whatever the

number is -- 508 is that you're only using part of it.

MR. TANEJA: Correct.

CHAIRMAN BROWN: And that part reflected in NEI 17-06?

MR. TANEJA: Correct.

CHAIRMAN BROWN: But one of your other statements said that all 61508 was all SIL completely.

MR. TANEJA: That's right.

CHAIRMAN BROWN: Is there other stuff in there besides that?

MR. TANEJA: Well, it is -- basically, the framework is they use a risk model in that standard which determines the SIL levels. So there's some calculations and they calculate the risk reduction factor based on your failure probabilities. And then it calculates failure probabilities.

And for each SIL level, it basically requires you to have certain reliability factor for this equipment. So the failsafe probability, fail dangerous probability. And then there is a method of calculating a risk reduction factor. And then --

CHAIRMAN BROWN: Stop. Okay. You're way -- Dinesh, you're way ahead of me. Too much detail.

MR. TANEJA: That's why we did not endorse it. I'm just telling you what's in the standard.

CHAIRMAN BROWN: What part did you endorse? Is it just two SIL levels or, like, SIL 1 and 3 or --

MR. TANEJA: No, it's basically just looking at the critical characteristics that are in 106439. So those characteristics, they were identified in I want to say Appendix D of NEI 17-06. They come from -- and so they draw a correlation to what parts of IEC 16508 does those activities, right?

So essentially, we are still following the TR-106439 process for doing dedication. We're going to take credit for SIL certification. So we want to make sure that the item that are to be verified in accordance with 106439 are being verified during the SIL certification process. So those items are correlated to IEC task, and that is captured in -- I think it's Appendix D of NEI 17-06.

CHAIRMAN BROWN: Okay. So some part of that appendix identifies the explicit sections that are covered by your endorsement?

MR. TANEJA: Correct, mm-hmm.

DR. BLEY: Dinesh, Dennis again. At the risk of muddying the waters further, a few years ago we were going through 17-06 before this recent revision. But we had a discussion about the SIL

process and why it was needed and what was being used. And I assume that's what people were pointing to. Is it too complicated or can you tell us what led to the revision of 17-06 and your issuing of the new Reg Guide 1.250?

MR. TANEJA: So staff has been basically providing continual feedback to NEI while they were developing 17-06. And so they issued Rev. 0 I believe was September of 2020. And there were a set of comments that we gave to NEI on that Rev. 0 version which they incorporated and turned around and issued a Rev. 1 in December.

So basically what NEI was looking for was more or less a clean endorsement of the document. And so they incorporated our comments and that's why there's a Rev.1 to it. So Rev. 0 actually was just a few months before Rev.1. Prior to that, we were working with draft revisions. Okay?

DR. BLEY: Okay. And we got involved somewhere back there, and I forget what brought us into that. But we did.

MR. TANEJA: Right. Because you may have discussed it during one of our digital I&C Integrated Action Plan briefing of the committee.

DR. BLEY: Yeah, it was one of those.

MR. TANEJA: Right.

DR. BLEY: So this is Rev. 0 of your Reg Guide.

MR. TANEJA: Right.

DR. BLEY: But up to this point, people have been using the SIL process, I think. And you've been looking at on a case-by-case basis. Is that right?

MR. TANEJA: No, nobody in the nuclear industry use SIL process.

DR. BLEY: Nobody has done it yet. You just had a plan for it. Okay.

MR. TANEJA: Nobody has done it yet as far as I know. I think all their commercial-grade dedication is being done to EPRI TR-106439. So they're waiting for us to bless this process.

DR. BLEY: I got it. But before this point because the general commercial dedication process was fairly general, it was possible to -- I thought it was possible to use it for I&C, although it was a little vague how you ought to do it and that some people had done it. But people use that for I&C stuff before, or this will all be new?

MR. TANEJA: So TR-106439 is still the endorsed guidance for doing the activity, right? So

I think the dedication is still going to follow 106439 for digital items. And they are going to do everything else that's required in 106439 except for doing commercial-grade survey.

So if they are buying a SIL certified product, then they have to do certain things for the NEI 17-06 guidance to assure themselves that they are getting the right -- you know. And that's where all these different tables come in to cross correlate what's in the TR-106439 and how that SIL certified component has demonstrated that they meet those requirements.

DR. BLEY: And you folks on staff who are issuing this guidance have been through that at a level. You're convinced it covers things like counterfeit parts and things of that sort well enough to be comfortable with it?

MR. TANEJA: Right, right, right. So I think we've put one clarification in our Reg Guide for the user to also guard against counterfeit. And I think --

(Simultaneous speaking.)

MR. TANEJA: Most of the SIL certifying bodies also take the due diligence of verifying the product that they're certifying doesn't really have.

So when we were observing some of these activities, we heard some horror stories. The horror stories are that people are selling components on eBay saying it's -- and selling SIL certification with them. And so this is global. I'm not talking about U.S. necessarily.

DR. BLEY: Right, but you can buy it here. Yeah, I've seen that too.

MR. TANEJA: Right. And I think that's where the red flags went up that, hey, how does one go about assuring that we are really getting a genuinely certified product and being used in safety application? So I think those are the oversight activities that are captured in NEI 17-06 --

(Simultaneous speaking.)

DR. BLEY: And I won't dwell on this all day, but I think the big difference in going to the SIL process and just the old fashioned safety grade approach is you're not as far into the internal processes of the vendors as we would've been under either the survey or the regular safety grade process.

MR. TANEJA: Correct. On a safety grade process, most of the licensees would issue a purchase order and then they would do four point inspections and all that during the manufacturing of these devices

and equipment. And they would be witnessing of their testing and all that as part of the requirements of their purchase order. So here we already have a device that's an end product.

Basically, it's available in the market to be used. Now the only thing the certificate is giving us is that they've done the due diligence to look at all those things that we as, let's say, a licensee would have looked at if you buying that from an Appendix B shop, right? I think that's really where the parallel drawn is, and that's how we got there, right?

DR. BLEY: I think I understand that part. What organizations actually do the -- I'll say inspections, I don't know what the right word is -- for the SIL certification?

MR. TANEJA: Okay. So in U.S., the dominant entity is Exida that does SIL certification. And they are accredited by ANAB. ANAB is ANSI National Accreditation Board that goes and audits Exida's work every year. Okay? So we had the opportunity to -- on multiple occasions to observe these audits.

And as a result of those audits, there were some comments that we provided to NEI and to ANAB where

ANAB went and actually enhanced their audit process because of our feedback. And so ANAB performs a lot of these accreditation activities to different entities like they do a lot of these equipment that's certified by FCC, for example, and all these kind of things. So there are different things that are being done in the industry to different standards. And ANAB basically assures that these things are being done right. For example --

DR. BLEY: Let me jump in with two quick things.

MR. TANEJA: Okay.

DR. BLEY: Can you spell Exida for me?

MR. TANEJA: E-X-I-D-A. It's on the slide on the fourth bullet.

DR. BLEY: Thank you.

MR. TANEJA: And now if you go to the website, they'll even show you the products that they have certified and they're certification, everything on their website.

DR. BLEY: Okay. And I don't know ANAB. What's that stand for, American National something?

MR. TANEJA: Okay. ANAB is ANSI, American National --

DR. BLEY: Oh, that is ANSI. That's just

their new name.

MR. TANEJA: Well, that is part of the ANSI that does accreditation.

DR. BLEY: Oh, part? Okay.

MR. TANEJA: So it's ANSI National Accreditation Board or something like that.

DR. BLEY: Okay.

MR. TANEJA: Right. So they have --

DR. BLEY: Thank you. I think it's fitting together much better. That was a very helpful discussion. But keep going.

MR. TANEJA: Right. So when the NEI started this effort in parallel, EPRI started a research activity. And so that research activity was to look at this efficacy of the SIL certification for nuclear power. And the first bullet identifies what that EPRI report is.

So NEI 17-06 kind of leverages some of the results of that EPRI research in building their technical case for why it's okay to do what we are doing here. So in that, EPRI -- I think EPRI came and gave us some presentation on their work a couple of times while they were doing this research through our bilateral agreement with EPRI. And they went and they looked at the work done by Exida. They looked at work

done by TUV in Europe. And they looked at -- I think at least they looked at three different certifying entities. So TUV is big in Europe.

And in U.S., ANAB also has entities all over the world, not only in U.S. But Exida is headquartered out of Pennsylvania. And Dr. Goble who is the primary individual in that entity has written a lot of books on this, and he's very knowledgeable. And he's very open to talk. I was hoping that we can get him to come and brief the subcommittee what exactly they do. But that would require some extra effort.

DR. BLEY: Yeah, that would be interesting.

MR. TANEJA: But he is a very interesting person. He runs a lot of these free seminars, Exida does, on different -- you know. So they have, like, one-hour webinars that they do, explaining what these things mean and how they do their work and everything else. So a lot of information is available out there right now. All right. So that's a little bit of background.

CHAIRMAN BROWN: Dinesh?

MR. TANEJA: Yes?

CHAIRMAN BROWN: You don't have to go back a slide. You made the comment on the SIL process

there's people out there they know how to do it. They've been doing it for years. Somebody has a product but it's a completed product. How does -- like a PLC controller for this, that, or the other thing as you talked about, how does this apply to one of our licensees who wants to upgrade their reactor trip equipment or safeguard equipment to digital? That's not a predetermined product that you have. It's a unique specific design relative to a specific plant. How does --

MR. TANEJA: Well, let's take an example, right? So we basically have accepted the use of Common Q platform sold by Westinghouse.

CHAIRMAN BROWN: Yes, I was going to -- that's one of the examples I was going to ask you to explain.

MR. TANEJA: Right. But what we did is we wrote a safety evaluation. We reviewed the product, and we said, yeah, it's a good product to use and safety application. But in parallel, Westinghouse went and got a SIL certification on that platform.

Now I don't know what their motivation was. But they may have been required to do that to market that product to some of these international bodies, nuclear plants. They may require that, hey, you have

to have a SIL certification in addition to that.

But when we evaluated that, we recognize SIL certification. But we really did not give much credence to it back when we did our safety evaluation. But we did ask questions about it, what exactly was done back then and all that. So that's, like, an example of how this thing is being done.

And talking to the NuScale people and the Rock Creek innovation of their HIPS platform, so when they built a prototype and when we witnessed the testing of the prototype that was a few years back, they were talking about trying to get a SIL certification on their product as well. Okay? So when you go and take a look at the Exida's website, they list a bunch of different logic devices, what they call -- the term they use. So these are, like, some small PLCs.

But most of those, like, Siemens or Honeywell or Allen-Bradley, so those equipment that these entities produce, they produce specifically for a safety application. Those are really not very elaborate. They are simple, small PLCs that can do a safety function highly reliably. And that's what they choose to get certified, even though they may have other PLCs that does, like, a massive control system application. But then it's hard to get those

certified. So they limit themselves to just getting the produce certified that are intended to be used in safety applications.

CHAIRMAN BROWN: Common Q is more complex than I would think a dedicated PLC operation from some controller somewhere.

MR. TANEJA: Correct. It is. It is. Right.

CHAIRMAN BROWN: And Common Q has been used in a couple places.

MR. TANEJA: Correct.

CHAIRMAN BROWN: Wasn't there another one like Triconex or something like that?

MR. TANEJA: Triconex has a SIL re-certification.

CHAIRMAN BROWN: Okay.

MR. TANEJA: But then again, Triconex originally developed for the process industry. They're very heavily used in petrochemical.

CHAIRMAN BROWN: Okay.

MR. TANEJA: And so when we reviewed that report, they already had a SIL re-certification on that equipment.

CHAIRMAN BROWN: But how it was applied was different. That's down in one of the plants in

Florida, I believe, if I remember correctly.

MR. TANEJA: Well, I think Diablo Canyon --

CHAIRMAN BROWN: Oconee used to also, didn't it?

MR. TANEJA: Oconee used the -- they used the Teleperm, I think.

CHAIRMAN BROWN: Oh, that's right. Thank you.

MR. TANEJA: Right, right.

CHAIRMAN BROWN: All right. All I'm trying to do is, like, Common Q is a part -- it's fundamentally a computer platform.

MR. TANEJA: Right.

CHAIRMAN BROWN: But there's all kinds of other stuff that connects into that. So what about all the other parts that comprise the rest of that system? Is it only the Common Q that gets assessed for these particular levels and all the rest of the connectivity is done some other way?

MR. TANEJA: Well, it depends on the manufacturer, right? What their purpose of getting a certification is, right? So like I said, if you look at the IEC framework and if you're following that risk reduction model and your safety instrumented system

is they word they us, SIS.

So you have some calculation that are done to determine how much risk that's acceptable to you, how much risk you want to reduce. And that determines how you want to architect the system and what SIL certification level of the equipment can be used to satisfy the overall safety goal of the design. So that safety goal model is the IEC model.

CHAIRMAN BROWN: Dinesh, try and be a little more specific. Common Q is applied. There's other modules that make up the overall reactor trip and safeguard systems in at least two applications. It's not just Common Q. There's all kinds of other little modules and everything else that perform that complete the safety function that the Common Q is just doing their calculation and it trips. But there's all kinds of --

CHAIRMAN BROWN: How do all those other modules get into this rigmarole of certification?

MR. TANEJA: We can ask Westinghouse. I think Warren may be online as to how they decided what was needed to be certified and why they went about it.

CHAIRMAN BROWN: Okay. Well, we don't need to do that here. This is --

MR. TANEJA: Yeah. We can do that during

the NEI's presentation.

CHAIRMAN BROWN: Okay. All right. Go ahead. I'm sorry. I'm just trying to get a calibration in terms of what we deal with normally.

MR. TANEJA: Okay. So --

MR. EUDY: This is Mike. I know Dave Rahn was raising his hand or trying to.

MR. TANEJA: All right. Yeah.

MR. RAHN: Thank you, Mike. This is David Rahn. I've been working with --

CHAIRMAN BROWN: You're getting feedback, Dave. I don't know what else is going on. I can't understand you.

MR. RAHN: I think someone is not mute.

CHAIRMAN BROWN: I can't hear whoever was talking, Dinesh.

MR. RAHN: I think whoever is talking is going on mute now. No, I just wanted to mention for Dennis and Member Brown the issues regarding the evaluation of Exida, for example. Three years ago, Jonathan Ortega and I attended one of the ANAB re-accreditations of Exida.

And with the effort to see if someone within the nuclear industry was going to be overseeing the process of certification and the accreditation of

the certifying body, what would they need to see to verify that the accreditation was very thorough and covered the criteria that we were concerned about? And so at that point, we were contemplating an industry body doing that. But what Jonathan and I saw was that although the ANAB process was very thorough in covering the management controls associated with performing a certification, it was weak on covering the technical criteria that are described in Part 2 and Part 3 of IEC 61508.

And those criteria are the kinds of criteria that we also like to see in safety-related applications of digital control. For example, it has to have a very thorough validation and verification program. And they have to be in control of procured equipment and assembly of the equipment and processes and quality of the personnel performing that.

There's a whole slew. So Jonathan and I were initially concerned that primarily the accreditation was covering the were the people qualified to do the job more than the equipment and actually designed, developed, and tested in a way that we would want to see for safety-related purposes. And so we made a recommendation to our working group where we met with NEI to enhance the re-accreditation

checklist to cover some of those criteria. And I want to make sure that because initially we didn't it was a thorough enough process.

But with the enhancement of the re-accreditation with this additional checklist, we believe it has been strengthened to the point where it's useful for providing at least a degree of oversight of how well the accrediting body performs its services. But we've also been fortunate in that both TUV and Exida are very thorough in identifying what criteria have to be meet the IEC 61508 standard. And in Exida's case, I believe it was an over 500 line item checklist of everything that's in that criteria.

And they've determined the degree to which the developing organization covers those criteria. So this is a very thorough process. And I just wanted to mention that that process -- the purpose of that process for our use is specifically to cover what we call the dependability characteristic that's described within IEC 106439.

And so there's functional characteristics. There's physical characteristics. There's other types of characteristics. This is only going after what we call the dependability characteristic. So the 106439 covers the

characteristics associated with digital I&C. And the dependability characteristic is what we are trying to meet what we leverage is SIL certification process which is very thorough.

DR. BLEY: David?

MR. RAHN: Yes?

DR. BLEY: Yeah, thank you very much for that. I appreciate it. By any chance, did you do a trip report or inspection report from your visit there? And is that available?

MR. RAHN: Yes, we did. There's a trip report part of the review of the trip that Jonathan and I took. And then there's another one, a follow-up one which was done by Greg Galletti and Dinesh. And we can get you the ADAMS accession numbers for those.

DR. BLEY: Yeah, I'd appreciate that. I think that would be very useful. And I appreciate your comments here. Christina will look for that. Thanks.

MR. RAHN: Okay.

MR. TANEJA: Yeah, there were two follow-ups I think Greg and I did. One was as recent as I think November, December of last year. And one was the previous year. So --

MR. RAHN: Yes, it was October of 2019.

MR. TANEJA: Right. And then I think Mike

Eudy has provided those ADAMS succession numbers for those documents, our trip reports, even though I guess we did virtually the last two.

DR. BLEY: Well, for Christina, I didn't see those in our list of documents. So if we can get access to those, it would be helpful.

MR. TANEJA: Sure.

MS. ANTONESCU: I think only one of the summary reports was extensive. The rest were very short, one paragraph or so.

DR. BLEY: Okay. Well, the long one is probably the one we want to see.

MR. RAHN: Yeah, you definitely want to see the October 2019 one.

MR. TANEJA: So let's --

(Simultaneous speaking.)

CHAIRMAN BROWN: Go ahead.

MR. TANEJA: No more questions? Move on?

CHAIRMAN BROWN: Yeah, I was looking at what we do next. It's a little after 11:00. The schedule agenda showed a break at 11:15. And right after this, you're going to go into the positions -- the guidance position 1, 2, 3, and 4, do an explanation. Would this be a good place to take a break for 15 minutes and then come back?

MR. TANEJA: Sure.

CHAIRMAN BROWN: Any objections to anybody?

DR. BLEY: Only thanks, Charlie.

CHAIRMAN BROWN: Only thanks. You and I are very attentive to that. All right. It's 11:05. We'll come back at 11:20. Okay. Is that fine, Dinesh?

MR. TANEJA: That's good.

CHAIRMAN BROWN: Okey-doke. Thank you.

(Whereupon, the above-entitled matter went off the record at 11:05 a.m. and resumed at 11:21 a.m.)

CHAIRMAN BROWN: All right. Well, let's go ahead and get going, and we'll move on to whatever your next slide is, I guess.

MR. TANEJA: All right. So my next slide is discussing the regulatory bases for our Reg Guide. So primarily to regulatory basis that allow for commercial-grade dedication. So 10 CFR 21.3 defines the basic component as commercial-grade item which has successfully completed the dedication process and also provides a definition for our commercial-grade item and dedication.

And the Appendix B, Criterion 3, design

control, Criterion 7, control of purchased material equipment and services include provisions for QA and quality controls that are applicable to acceptance and dedicating process of the commercial-grade digital I&E items. So basically, what our regulations say is that one can conduct a dedication activity. But the entity that's conducting the activity must have an Appendix B program and conducted under that quality assurance program.

So those are the primary regulatory bases for performing dedication tests. And that's really the technical -- I mean, the regulatory basis for our regulatory guide. So we endorsed NEI 17-06, Rev. 1 with some clarification.

There were no exceptions taken to it. So the clarifications are really intended to highlight some areas of focus. So the endorsement of Rev. 1 is basically saying that we are endorsing using of the SIL certification to support the acceptance of commercial-grade digital equipment that is being dedicated as a basic component and in accordance with EPRI TR-106439. So still the driving guidance document is the EPRI TR-106439.

So what we are really using in NEI 17-06 is supplementing our work process of TR-106439 and

using these SIL certificate as a method of verification of commercial-grade survey. So under the clarification position number 1, I think what we are basically saying that the NRC considers SIL certification to be a commercial-grade survey for the purposes of Part 21. So I think the reason why we identified that was that we are trying to draw an equivalency of our regulatory framework to the activities that we are trying to endorse here.

So the activity of certifying a component is essentially a commercial-grade survey activity as we call out in Part 21. So essentially saying that the certifying body services and verification of SIL certification to be adequate for verifying dependability critical characteristics. The other clarification was that the -- it's basically dedicating entity that dedicates the services of a certifying body should not rely on work done by another NRC licensee.

So if another licensee has used a SIL certificate in their dedication activity, the dedicating entity because it's been used once doesn't automatically assume that they can use it. They have to evaluate it according to their regulatory framework and the regulatory basis and see if that can be used or not. So that clarification was added. So it's not

like blindly just, hey, XYZ used it so I can use it kind of a step.

DR. BLEY: Dinesh, is that a big deal or is that almost a pro forma check?

MR. TANEJA: Well, it's -- I mean, we are just basically throwing caution to the wind saying that don't just blindly accept licensee's activity into your own process. They may have a rationale and reason why it's suitable for them. You have to make your own determination, whether what they did is suitable to your task that you're performing or not.

DR. BLEY: Okay. I don't know if that's hard to do or not.

MR. TANEJA: Well, I mean, it's like --

DR. BLEY: It sounds pretty easy.

(Simultaneous speaking.)

MR. TANEJA: Yeah, we basically felt that they should not be, like, when a licensee says, oh, XYZ did that. So I'll just -- since they did that, I can do that too. Now what we basically are saying is, well, if you're going to do that, make sure that it applies to you adequately.

DR. BLEY: Okay. That's good. Maybe when NEI gets up they might have something to say about that. I'd be interested if they do.

MR. TANEJA: Right.

MEMBER HALNON: So this is Greg. That doesn't apply to a fleet, right? I mean, they can do --

MR. TANEJA: Right. The fleet is basically I guess the same outfit, right? It's within their own. But even in the fleet, let's say that one other facility licensing basis may be different from the other facility's licensing basis.

MEMBER HALNON: Yeah, okay. That's fair. You at least have to meet your licensing basis. I agree.

MR. TANEJA: Correct, right. So it's due diligence on the part of the dedicating entity to make sure that it's not being blindly followed. That's all. So the other thing --

CHAIRMAN BROWN: Yeah, Dinesh. Go back to that again.

MR. TANEJA: Yeah.

DR. BLEY: Can I continue a little bit, Charlie?

CHAIRMAN BROWN: Yeah, go ahead. Go ahead. Go ahead.

DR. BLEY: It sounds like just a normal rational thing to do. But were there examples in the

past where this was not done well and got something into trouble?

MR. TANEJA: Greg, do you have any examples of where --

DR. BLEY: I'm not looking for specific ones. Just I wonder if some things had applied for you guys.

MR. GALLETTI: No, it wasn't -- again, this is Greg Galletti from the NRR staff. It wasn't that we were trying to avoid previous mishaps. Really it follows in the normal processes that the industry currently uses.

And just as an example, when you think about the audits that are currently done by a NUPIC organization on behalf of the licensees, the audit is completed. The audit report is distributed to the members of the NUPIC organization. But they themselves have to evaluate that audit within the context of their own quality and programs -- licensing programs -- to ensure it's adequate and meets their desires and requirements before they accept it.

DR. BLEY: That's kind of what I wanted to hear. And --

MR. GALLETTI: Yeah.

DR. BLEY: -- I just wondered if there

was something more going on here.

MR. GALLETTI: No, no. It was to keep this process in line with what's currently accepted within the industry.

DR. BLEY: I'm done, Charlie.

CHAIRMAN BROWN: Okay. I got messed up on this particular Item B in terms of how it was phrased. It fundamentally says, to be clear, each dedicating entity should dedicate the services of each certifying body whose certificates the dedicating entity wishes to rely on and should not rely on dedication by another NRC licensee. And I went up and got -- after going through that about five times, I had to go take an Advil just because my head was exploding.

I lost track of dedicating entities, certifying bodies, and the licensee. I mean, if I'm a licensee and I wanted to get something dedicated, I'm not the dedicating entity. I'm the requester.

(Simultaneous speaking.)

CHAIRMAN BROWN: And a certifying body certifies a dedicating entity. So I really lost the bubble on this.

DR. BLEY: I kind of suggest if you took a look at our transcript what both of you said is a whole lot clearer than that paragraph.

MR. TANEJA: So let me kind of break it down. A dedicating entity is an entity that's performing the commercial-grade dedication activity. A dedicating entity could be the licensee themselves, could be supply vendor that's supplies safety-related components to the nuclear industry. And they are dedicating and they are then marketing it as a basic component to the licensees. So the purpose of this document, we basically said, a dedicating entity is the one that is actually performing the dedication of a commercial-grade product whereas a certifying body is basically a third party that does just certification of a component to the conformance to the IEC 61508 standard.

DR. BLEY: That would be like Exida?

MR. TANEJA: That would be like Exida, right? A dedicating entity could be a licensee or it could be people like, I guess, there are suppliers out there that do specific dedication and all that. And then they market the products, right?

I think there's a number of suppliers out there that do these services for the nuclear industry. And so the dedicating entity could be the licensee themselves. I know TVA used to do a lot of their own dedicating in house. They have their own methods of

doing that, and they did that in house.

(Simultaneous speaking.)

DR. BLEY: -- and oversee that occasionally?

MR. TANEJA: So the NRC essentially inspects these periodically. These vendors that do -- they have an Appendix B program. The dedicating entity has to do the work under the 10 CFR Appendix B program.

So these outfits do have an Appendix B program. And we do inspect them on a periodic basis, how they're performing commercial-grade dedication. So the certifying body is the one that is conducting certification activities to IEC 61508.

And then there is the third person that we are talking about. It's an accrediting body. Accrediting body is in the U.S. is ANAB. In Europe, I forget the name of it. There is an entity in Europe that is essentially like the ANSI over there that does the accreditation activities.

So that's really where the clarification is. The dedicating entity is actually doing the complete scope of dedication, not just the little part that we are taking credit for on the certifying body's work. But they are doing everything that's required

by TR-106439.

CHAIRMAN BROWN: It's not the way I read it.

MR. TANEJA: Sorry.

CHAIRMAN BROWN: I understand. If I'm a licensee, just make it simple. I'm a licensee. I've got a design that I need to get certified as a commercial item. Okay? A commercial item that needs certification.

I've designed my system. Now I have to go find out somebody who's qualified to do certification, or I have to consider myself qualified and do it and then get a certifying body to okay it. Is that right?

MR. TANEJA: No, no.

CHAIRMAN BROWN: Or do I go to the accrediting operation?

MR. TANEJA: No, so the way it is going to be is a licensee has the ultimate responsibility to assure that their design has the components that meet the safety classification for that given device. So if there is a basic component, the licensee is responsible for that. They can procure that component from Appendix B supply house like let's say from Westinghouse.

They can just write a purchase order and they can buy the stuff from them which would be sold under their QA program. Or they could do the commercial-grade dedication on a commercial product that they just go out and buy commercial product. And then they perform the dedication themselves.

Or they can go out to an outfit. I think there's a company like Paragon comes in mind that sells reverse engineered parts and sells. But they have an Appendix B program, and they perform commercial-grade dedication on the parts before they sell it to the licensees.

So the dedication entity is it could be that. I could be Westinghouse. They could have dedicated it before selling it, or it could be licensee themselves.

So you have basically any combination of people that can do the dedication, right? A certifying body is a third party that's just simply doing certification of digital equipment. And it certifies that, hey, this equipment meets IEC 61508 requirements SIL level. That's all they do.

Now the accrediting body is the body that makes sure that the SIL certifying bodies are good people. They're doing the work that is done under a

controlled environment and it's not a hodgepodge of work that they're doing. So it's not like they're saying, give me this much money and I'll give you a certificate.

I'm just throwing out a very bad example. But it's a valid activity being performed by the certifying body that gets accreditation. So those are the three bodies that kind of are there.

So this one is a dedicating entity. What we mean is it could be a licensee. It could be anybody else. What we are saying is that just don't blindly assume that if somebody else has already used that SIL certificate and their dedication process is going to work for your also in your application.

CHAIRMAN BROWN: Okay. Let me -- gee, my head is exploding again. Just reading your B (phonetic), each dedicating entity should dedicate the surface of each certifying body. I'm a licensee.

MR. TANEJA: Right.

CHAIRMAN BROWN: And you said I can be my own dedicating entity?

MR. TANEJA: Correct.

CHAIRMAN BROWN: Now why do I have to dedicate the surfaces of each certifying body if I'm going to dedicate it myself?

MR. TANEJA: Well, you're buying the SIL certificate from them. So what we said in the Clarification 1 that the purposes of Part 21, what you're really doing is you are dedicating the work that's being done by the certifying body. Okay? So what you are saying is all the due diligence that you're doing to check on the certifying body is essentially a dedication task.

So you are saying, hey, I am dedicating the services that you are providing. Okay? So you're buying the services of a certifying body and you're using those services in a safety-related application. So by virtue of that, what you're doing is you're dedicating their services.

This is our regulatory framework, Charlie. I'm sorry. We're just trying to make this clarification so we basically keep everything legal.

MR. BENNER: Well, it's different pathways, Member Brown. So you're right. I mean, an individual licensee could really just go through the dedication process for our component.

What we were asked to do by industry is say, hey, there are SIL certifications out there. How can licensees leverage that? So we walk through how licensees could leverage that.

And because ultimately the licensee bears the responsibility for any dedication activities that they do, they have to do their due diligence on a certifying body. So where I think you're going with his is, boy, that doesn't seem very efficient. And I would agree that if each individual licensee is going to have to do their oversight of the certification bodies, it would not be very efficient.

It probably would not offer much help to licensees. But I think the goal of industry is once we get this process in place, then we will have Exida look at -- we will all have looked at. And there could be other accrediting bodies.

There will be -- much of this work will be done generically, just like it currently is for different commercial-grade dedicated items. So it ends up not falling -- completely falling to the responsibility of individual licensees. But we had to write our process in a way both paths were viable, that a license could choose to do this themselves or they could choose to use an accreditation body.

So it is complicated because there are a bunch of different paths, right? Obviously, the simple path is buy is from an Appendix B vendor. There's already a path of just do the commercial-grade

dedication yourself.

We're really now creating two paths here in doing -- in leveraging the SIL certification. It's do your own oversight. Have a licensee do their own oversight of the SIL certification process to leverage that in their commercial-grade dedication process, or use a service like Exida to do some of that for you. And I think as this gets indoors, it'll be that latter path that will be used. And it'll be that latter path that truly gives the licensees, right, a less resource intensive path to using these components.

CHAIRMAN BROWN: Okay. Let me interrupt you there because you use the -- you kept using the word, accreditation body. And the way I viewed what you all have been looking at and when I looked at the NEI slides, as a licensee, I don't want to do the dedication myself. So I go to somebody like Exida who is an accredited certifying body.

And they certify my design meets the SIL requirements. Exida was an accredited certifying body, not an accreditation body based on some of the other view graphs. That's like ASME or ANAB or whoever they are that do this for the other stuff.

There were three circumstances. And that's what I'm getting confused on is if I'm a licensee

and I don't want to do -- and I've got to get my stuff certified as a commercial item that's okay, I can go to somebody else who accredited to do that, who is certified to do that, in other words, somebody like Exida. So they go through whatever reviews they do and say, yeah, your device qualifies as a commercial item with a SIL level of what the appropriate thing is.

But they've been accredited to do that. That's the way I was reading all your things. You kept throwing the accreditation in on with Exida. They were not an accreditation body from what I understood the other view graphs.

MR. BENNER: Right. But for there to be a SIL certificate, there has to be a certifying body.

CHAIRMAN BROWN: Yeah, that's Exida, right?

MR. BENNER: Right. They're the ones who generate the SIL certificate.

CHAIRMAN BROWN: So the dedicating entity goes to Exida to get --

MR. BENNER: Well, maybe, maybe. Let me just step it back as to in the international community, you -- that might be enough, right? Other regulatory bodies may say, you have your SIL certification.

That's good enough. You're done. We did not say that because we have Appendix B.

So there is an inherent equivalency between SIL certification and Appendix B. So what we have created here a pathway that SIL certification can be leveraged in your commercial-grade dedication process. So this other piece of the accreditation bodies, right, is also what we are leveraging to ensure that what is in that SIL certification, right, passes muster so that we have confidence we can use that in a licensee's commercial-grade dedication process.

CHAIRMAN BROWN: That means Exida has to be accredited.

MR. BENNER: For our purposes, I believe that's correct. But I'll let Greg correct me as to whether an individual licensee could perform their own oversight of Exida to make that conclusion or Dinesh can weigh in.

MR. GALLETTI: They could. It would not be -- I'm sorry. This is Greg Galletti again with the NRC. They could. It wouldn't necessarily be an efficient way to do it. And that's why we're looking to leverage the accreditation process as part of these activities.

I think in essence what it's saying is --

and Dinesh pointed this out -- the licensee, in this case, let's say the licensee is the dedicating entity. The licensee as part of their dedication is utilizing services of the certifying body. And as such, that certifying body in essence is a supplier to them. And so just like any other activity at the nuclear power plant, if you're purchasing something from the supplier, you have to do some due diligence to ensure and put that supplier on your ASL in order to do procurements.

And so in essence, that's what this is really going at or trying to get to. In other words, if I'm Licensee A and I have a Westinghouse on my ASL, Licensee B can't simply put Westinghouse on their ASL because Licensee A has them on there. They have to do their own due diligence and evaluate that supplier in order to purchase from them. Again, that's essentially what this is getting at.

CHAIRMAN BROWN: Okay. I'm now looking at Slide 13 from EPRI -- from NEI that certification bodies have standardized rigorous reliable evaluation processes. TUV and Exida are certification bodies. Accreditation bodies ensure that the certification bodies are consistent and trustworthy. And that's where I'm getting confused.

I mean, if I'm a licensee and I've got something I need to be certified with a SIL level, I go to somebody who's approved to be a certification body by an accreditation body to get my SIL certification. I don't know what that makes me as the licensee. I've got the hardware or the design, and I want somebody to certify the design that it meets SIL levels. So I go to Exida or TUV. And they've been certified by accreditation bodies that have a rigorous reliable evaluation process that can issue a SIL certificate, tubing for my equipment as a licensee.

MR. GALLETTI: Again, this is Greg Galletti. I think we're mixing up a couple of things here. But I understand your point. I could be a licensee or any other entity and I produce a product that I want to have SIL certified, I would go through that SIL certification process as you described it.

That's really not what we're doing here. What this whole purpose of this exercise is, is to say, I am a licensee and I want to dedicate something. And as part of that dedication, I'm going to leverage a SIL certification that was done on a piece part or that system or that component already. It's not that I as the licensee and the manufacturer are seeking a SIL certification. I think that's really what we're

trying to distinguish here.

CHAIRMAN BROWN: So what you're saying is these other folks have already -- it's for products that they've already certified?

MR. GALLETTI: Yes. Typically, that is the case. At least --

CHAIRMAN BROWN: If you can find a product like the Common Q platform which has already been SIL certified, you can go and get that and use that without doing anything else?

MR. GALLETTI: Well, no, you would go through and use it. But you would do it within the context of your dedication program. And so what you would be doing with that SIL certification as we pointed out within the context of this framework is you would be leveraging that SIL certification as part of your dedication activities as it relates to verification of the dependability characteristics of whatever that is. You would still have to complete the dedication for performance and physical characteristics for whatever that system is. All this effort in NEI 17-06 is doing is leveraging the SIL certification for the dependability evaluation as part of the dedication.

CHAIRMAN BROWN: Okay. I quit. I give up. Greg and Matt, I'm glad I was in the Navy.

MR. TANEJA: Yes.

CHAIRMAN BROWN: Cradle to grave.

MR. TANEJA: A little different here, right?

CHAIRMAN BROWN: Cradle to grave.

MR. TANEJA: Exactly.

CHAIRMAN BROWN: These nuances are lost on me. I know you all had to deal with it forever. Let's go on. I'm sorry. Hopefully I haven't confused anybody else but me. Go on, Dinesh.

MR. TANEJA: So the Item 1(c) basically I think what we have in the NEI guidance is that they are saying that if we are observing an accreditation of a certifying body's work, it can be done longer than three years. And if they're doing good work, then I don't need to look at them every three years. So I think our clarification is basically saying that, hey, this is the accepted practice that we want you to observe their work at least every three years. Okay? So that's just a straightforward clarification.

CHAIRMAN BROWN: Yes.

MR. TANEJA: Okay. And then again we just wanted to clarify on 1(d) that the term -- use a term, basic component, in our regulation also includes not just produced under an Appendix B program but also a

dedicated commercial-grade item. So it basically makes the dedicate commercial-grade item equal to what have been produced under a QA program -- Appendix B QA program. So 1(e) is -- here, I think, because certificate has an expiration date on it.

And we are basically here highlighted that, hey, pay attention to the expiry date of the certificate and look at potential of a counterfeit and fraudulent SIL certificates. Don't just buy something. Verify that.

So it's just basically putting caution to the wind. And then we are position 2. We're talking about endorsing the parts of IEC 61508. And that's as described in NEI 17-06, right?

So the parts that are being endorsed are the ones that are described in NEI 17-06. So there is a Section 6.3 in NEI 17-06. So we are basically saying that the dedicating entity should verify that the work that the certifying bodies of accreditation make sure that they meet the guidance that's in Section 6.3 of NEI 17-06.

And then B is simply saying that if IEC 61508 gets revised, right now it's Edition 2.0 is what we looked at. And the comparison was made with Edition TR-106439 on the particular characteristics. So we're

saying if this gets revised, a dedicating entity needs to verify it doesn't impact the dependability characteristics that have been identified in NEI 17-06.

So it's essentially saying that, hey, we're not going to come back and re-look at that. It's up to the dedicating entity to verify. The later revisions do not impact the basis of the NEI 17-06.

So 14-02, their draft guide or the Reg Guide endorses the use of ISO/IEC 17065. This is basically a standard that a certifying body performed their work by. So their work process meets the requirements of 17065. And that's really what the accrediting body uses to do the audits to make sure that the work is being done to a rigor that is necessary for these activities. So that portion of 17065 is being endorsed because we are kind of accepting that process in NEI 17-06.

CHAIRMAN BROWN: Is that the -- there's a lot of references to what I call the old method which was a survey method. And is that you're talking about here? Is that 1.164, or is that --

MR. TANEJA: At the end of the day, the commercial-grade survey that a dedicating entity needs to perform to dedicate digital equipment. Instead of doing that, what they are saying is that if I have SIL

certificate that is of a good quality, then this is all getting down to, you know, that there's a genuineness to that certificate. The work is being done by a credible entity and they are giving you a certificate that really does mean something, then you can use that to avoid doing commercial-grade survey yourself. That's all.

And that's really the whole purpose of NEI 17-06 is. And that's what we are endorsing. And I believe there is a figure in NEI 17-06 that kind of lays out the overall dedication activity and what parts are being substituted by using a SIL certificate. And I think that may be in the NEI's presentation, that little figure that comes out of NEI 17-06.

(Simultaneous speaking.)

CHAIRMAN BROWN: Yeah, I think you're right. I think you're correct on that.

MR. TANEJA: So that would probably help in understanding that what part of the dedicating activity is being leveraged. That's it. So it's just a little bit of it. You still have to do the other requirements that are in TR-106439 regardless.

So those are the three clarifications that we have in the Reg Guide. It really didn't change what we have in NEI 17-06, Rev. 1. I think the only thing

that -- I point out most of these are clarifications. The only thing is I think for doing the observations of a certifying body's accreditation, the NEI 17-06 says that initially do it at three years.

But if you find that these good guys, then you can adjust that observation period based on the performance or based on their -- so we basically disagreed with that reason now. We've got to do it at least every three years. And I think that's the only clarification that is counter to what's in the NEI 17-06.

CHAIRMAN BROWN: Yeah.

MR. TANEJA: And the rest of them are just basically caution and clarifications. So this document was sent out for public comments. And the only entity that provided comments was NEI, and we received five comments from NEI on the draft guide that was issued.

And so it essentially did change our Reg Guide. And most of the changes that we had to make (audio interference) things correctly. And comment 1, so we did -- basically it was where we said that the licensee or dedicating entity are relying on the results of a commercial-grade dedication form on behalf of the licensee remains individually responsible.

So there was a question came up that what do we really mean by that you cannot accept somebody else's work. So we added this additional clarification to this regulatory position to just simply say that, yeah, you can probably leverage that work. But you got to do the due diligence to make sure that it applies to your work that you're doing and your framework that it works for you.

So that essentially was the clarification that we added to the staff position 1(b). So comment 2 was on Section B of DG-1402. And that we revised to state that.

So I think here the words the words that we had were a little bit confusing to the extent that so we said that the SIL certification process is done in accordance with IEC 61508. So what NEI clarified that IEC 61508 doesn't tell you how to do the certification activity. It just tells you what the technical requirements are for different SIL levels.

So I think we just changed these words and clarified that delivered the SIL certification process that relies on the IEC standard. So that was just making sure that we are not saying that the process resides in IEC 61508. It does not reside in there.

So comment number 3, we revised Section

B to add this sentence there that the NRC staff considers SIL certification to be a commercial-grade survey for the purposes of Part 21. So in our regulation, we are saying one method is to perform commercial-grade survey. We do not have in our regulation anything about a third party certification.

So we are drawing a parallel here that to stay in compliance with Part 21, we are correlating the SIL certification activity as a commercial-grade survey. So this was added to the Section B to make that clarification which we had the regulatory position and clarification already. But it was in the body of Section B.

So the recommended edits, we agreed with the comment. But we did not entirely agree with the recommended edits on comment number 4. So we essentially revised the staff position 2(a) to indicate that NEI 17-06 is leveraging an existing certifying body's accreditation process.

Okay. So it's like we are not -- whatever their existing process of accreditation is, is what we are leveraging. We are imposing any additional accreditation activity on certifying bodies. So the comment number 5 is the one that we disagreed with.

This was the recommendation on the reduced

frequency for observing the certifying body's certification process. So that we didn't make any changes to our draft guide as a result of this comment. These were the five comments, and they really did not change the Reg Guide considerably. It was just tweaks. And I think that's the end of my presentation.

MEMBER REMPE: So I have a question. This is Joy.

MR. TANEJA: Go ahead, Joy.

MEMBER REMPE: At the beginning of the presentation this morning, Dennis and Charlie made some comments. And I believe you said, yeah, probably that would be a good idea regarding some clarifications about the intent and what other options are still available associated with this Reg Guide. Are you planning to make some changes? Or what's your schedule for issuing this Reg Guide at this time?

MR. TANEJA: Mike Eudy, you probably have a better handle on the schedule.

MR. EUDY: Yeah, this is Mike Eudy from Office of Research for NRC. In terms of schedule, really it depends on if ACRS has issues and there's going to be a full committee, et cetera. But we're poised to release the Reg Guide once we've dealt with ACRS issues.

And that can be next month or it could be months from now. So it really depends on what edits or suggestions ACRS may have through a full committee on changes to the Reg Guide. So we'd have go get through that. Or if there isn't anything, then we're on a fast track to be issued I would say next month.

MEMBER REMPE: Okay. Well, as you know, we're scheduled right now for September to have a letter. And today I've heard that Charlie wasn't able to get some of the documents he needs for doing this. And so I'm just kind of wondering how this would affect schedule. But we'll discuss it later in this meeting, I assume.

MR. EUDY: Okay.

MEMBER REMPE: Yeah, but we don't have a full committee meeting in August as you know.

MR. EUDY: I think Christina mentioned September 21st.

MEMBER REMPE: It would be a little earlier, I believe.

CHAIRMAN BROWN: The first week in September.

MS. ANTONESCU: Mike, I mentioned September -- the first week of September. All our full committee meetings are in first week of the month.

MEMBER REMPE: Right.

MR. EUDY: Okay. Thank you.

CHAIRMAN BROWN: If we can get a hold -- this is Charlie. Based on all the other discussions -- and I don't know how Dennis feels because I would like to make sure he's satisfied. If we can get that IEC document just so we can see it, we could probably -- based on all the discussion and everything else, I've got to figure out what I said back at the beginning and a couple of the -- a little clarification that Dennis and I mentioned.

If we had this in the next week or so, that would give at least me time enough to take a look at it. I'd just like to see what the thing says relative to what the NEI document is referring to. But you all have answered a lot of the questions that I had.

I don't know whether Dennis is comfortable yet. But if I get that and can take a look at it, I think we could probably pass on any questions we had and then make sure we resolve those at a full committee in September. At least we would get that letter out of the way. Joy, is that consistent with your thoughts, if we can do that?

MEMBER REMPE: That would actually be good to have that confirmed during this meeting. And I was

a little puzzled where we were in the process. But based on what Dinesh said, I think some knowledge transfer to make sure that everybody -- you'll probably have to access the standard yourself.

But they can provide you how to do this. I get the point about you can't be passing it from one person to another. But I think it's doable. It's just that you'll need to get trained on how to get into this system.

CHAIRMAN BROWN: If somebody assists Christina, make sure we can get it and send it to Dennis and I and whoever else on the committee who wants it.

MEMBER REMPE: I think it's a little more complicated than that. It's sort of like what we do for some other processes that we review. But yes, I think it'll be possible as long as NRC has access to it which Dinesh has assured me we do.

CHAIRMAN BROWN: Dennis, do you want anything more?

DR. BLEY: Not much. Real quickly, in the old NRC internal website, I could always find the standards. The new one made it difficult and I had to get help. But we can get help and we can get in there and see it.

MS. ANTONESCU: Yes, I'm with you, Dennis.

DR. BLEY: I would like to be able to see that trip report. And as Charlie said, your discussion, all of you, your discussion this morning was extraordinary helpful and clarified many things that I was completely lost in. And I think I see how it all hangs together.

Even in -- I think it was Charlie and I said something about in the new Reg Guide, it wasn't overly clear why it was here. Now back in your Section C on the guidance, it's spelled out pretty well. But it was a little thick to get through.

I think a word up in the purpose to say you're extending the previous work to the SIL would be helpful. I don't think you ever do this, but this has so many threads going back through EPRI documents and NEI documents and NRC documents. A little roadmap to that history in front of this Reg Guide would help almost every reader.

And I think most of the industry and all of you folks have been involved -- you said for over six years. For new people coming at it and there will be new people coming at it, that could be a big help. But that's kind of up to you. I know it isn't the way you usually do things in Reg Guides.

MR. TANEJA: Okay. So I have basically

three takeaways so far. So I have I can help Christina try to get the ICE 61508 standard with the IHS and the observations of the accreditation activities. We do have those trip reports. We'll share those with you. And we'll look at the upfront material of the Reg Guide and see if we can provide these clarifications upfront on the purpose. And those are the three takeaways I have.

CHAIRMAN BROWN: That's what I remember. Hopefully, we can get a transcript fast enough that you can go back and look all the wordsmithing we did as we led in that would help you understand what you think you may want to expand. I don't know what the timeframe is on transcripts.

MS. ANTONESCU: We will ask Sham (phonetic) to help us. Thank you.

MEMBER REMPE: This is Joy. Before you -- well, I'm not hearing Dennis' request about some background on the path to get here and that it would help. Instead of saying I know you don't usually do this, is it has it never done in a Reg Guide?

I'd like the staff to respond to that a little more clearly, that, no, we just can't do this versus, well, it has been done occasionally. Or I'd like a little bit more of a response from the staff

about doing that. Did I push a little bit harder on that one?

MR. TANEJA: No, I don't think so, Joy. I think we have the flexibility of Section B to paint the picture clearer. I believe we made that attempt. We can definitely go back and see if we can clarify based on the comments that we got together.

MEMBER REMPE: Thank you.

DR. BLEY: A little roadmap picture would make it perfectly clearer to me.

CHAIRMAN BROWN: Not paragraphs of sentences but a little chronological diagram of one line that shows, hey, here's the pathway that we've evolved in over whatever the relevant period of time is.

MR. TANEJA: Okay.

CHAIRMAN BROWN: Anyway, I agree with Dennis. A picture would be worth 1,000 sentences.

DR. BLEY: To your question earlier, Charlie, last night I told Charlie even though it's going to be over a month to our full committee meeting, I didn't think I'd be able to sort things out by then. After today's session, I'm confident I can and I'm sure the committee can as well.

CHAIRMAN BROWN: Yeah, I know I can and

that's why I think we can go ahead and get on with -- the discussion has been very, very helpful even though I may be still a little bit confused from my past associations. I think that won't create a problem. So getting the documents and the transcript so you can see what we said and then a suggestion on a little chronological diagram to show the progression. It's very convoluted when you read through it with all the TRs and the EPRI document stuff. Your brain explodes. You just can't keep track of it.

So that would be useful. And I think we ought to proceed now. At least I agree that we ought to go ahead and head on off and try to get a full committee meeting. Your presentation would obviously have to be shortened up a little bit, but so would NEI's because theirs is very long. So we can talk about that later.

MR. TANEJA: We'll work with you on a full committee presentation.

CHAIRMAN BROWN: Okay.

MR. TANEJA: We're probably just focus on the changes as a result of this meeting.

CHAIRMAN BROWN: Yeah. And NEI, is NEI going to be wanting -- we got almost a full committee here. NEI is going to be done their presentation next.

And I just checked, and I noticed Dave Petti is now here also.

So we've got nine out of ten of our members are here. So it would be -- NEI is like in the tens. What are you, 40 pages or 40 slides or something? I forgot what the number is. All right.

(Simultaneous speaking.)

CHAIRMAN BROWN: Pardon?

MR. EUDY: I saw 49 slides.

CHAIRMAN BROWN: Yeah, okay. I think it was up there. So we have to fit this in to what timeframe, Joy, an hour and a half or two?

MEMBER REMPE: You've got until -- wasn't it -- have Christina help me, but I thought it was until, like, 4:00 p.m. East Coast Time, right, Christina? And so it's more --

CHAIRMAN BROWN: I mean for full committee.

MEMBER REMPE: For the -- oh, I'm sorry. For the full committee, we haven't done the agenda yet for the full committee meeting. But usually -- we usually have the presentations don't last more than an hour and a half.

CHAIRMAN BROWN: Okay.

MEMBER REMPE: So --

CHAIRMAN BROWN: All right.

MS. ANTONESCU: Around two hours. Yes, that would be sufficient.

MEMBER REMPE: Yeah.

CHAIRMAN BROWN: Okay. Two hours ought to be -- we ought to be able to cover it. We'll make sure it covers it in that timeframe.

MEMBER REMPE: Sorry. I was distracted trying to respond to someone else and all that. And I thought you were talking about this afternoon.

CHAIRMAN BROWN: No, no. That's fine. No, we're good this afternoon. So all right. Dinesh, I take it you're done. And the next --

MR. TANEJA: Yes.

CHAIRMAN BROWN: Okay. According to the schedule, let me get that back up, the agenda, we had until 1:00 o'clock. It's only 20 after 12:00. So --

MS. ANTONESCU: I think we can break now, Member Brown, and then start fresh.

CHAIRMAN BROWN: Yeah, that's what I was going to do. Are we required to start at 2:00?

MS. ANTONESCU: I think it would be best. The expectation would be probably 2:00 o'clock.

MEMBER REMPE: Well, could I interrupt? And if folks can, you have more flexibility with a

subcommittee meeting if everybody from the staff and folks listening in and NEI are okay with it, you could go ahead and start earlier because they have a lot of slides.

MS. ANTONESCU: Yes, yes. That makes sense.

CHAIRMAN BROWN: I was going to suggest -- it's about 20 after 12:00. I was going to suggest that we reconvene at 1:30 as opposed to 2:00 o'clock. That would be about an hour and ten minutes.

MEMBER REMPE: I think that would be a good idea.

CHAIRMAN BROWN: Christina, no problem --

MS. ANTONESCU: Yes, that would be great. Thank you, Member Brown.

DR. BLEY: So 1:30 you said, Charlie. And maybe --

CHAIRMAN BROWN: Yeah.

DR. BLEY: -- you could ask NEI any of their slides that replicate what the staff has already gone over they could skim through pretty quickly.

CHAIRMAN BROWN: Yeah, we'll make that point. They're on the line now. I presume they're hearing us. Yes or no?

MR. NACK: This is Andy Nack. I'll be

presenting for NEI. Yeah, I'll make sure I skim over stuff that we've already covered.

CHAIRMAN BROWN: Okay, yeah. And if we start asking something that we're already answered, we'll try to get that cleared out, if we can remember that far. All right. We'll recess here at 12:20. We'll reconvene at 1:30 and to begin the NEI presentations. Okay? All right. Hearing no disagreements, we will -- this meeting is recessed for the period until 1:30.

MR. HECHT: Charlie, this is Myron. Sorry. Just before you go, Dinesh was correcting items and there were a couple that I captured that I'm not sure he totally got. And then --

CHAIRMAN BROWN: Okay.

MR. HECHT: -- one of them was that I think it was you who asked what parts of 61508 are being covered in 1704. In other words, not all of 61508 is being covered. And the other one is -- in other words, what parts of it are being endorsed here? And the other one was a question that really didn't get answered before. But Dennis had asked is what's the relationship be 106439 and another standard coming from EPRI 51 -- or 56.52 which was 102 -- I'm trying to find it now and I can't -- but 102260.

CHAIRMAN BROWN: Yeah, I don't remember that. I remember Dennis talking about 56.52.

MR. HECHT: Well, 102260 --

(Simultaneous speaking.)

MR. TANEJA: Yeah, I think what I did is when I said update the front matter of the purpose and then draw a figure that would be helpful included all these discussion to be there. But I took a note of it. We'll make sure that we address that.

MR. HECHT: Okay.

CHAIRMAN BROWN: Okay. All right. Thank you, Myron. All right. if that's it, does anybody else have any input?

(No response.)

CHAIRMAN BROWN: Okay. We'll now recess at 12:23 and reconvene at 1:30.

(Whereupon, the above-entitled matter went off the record at 12:23 p.m. and resumed at 1:32 p.m.)

CHAIRMAN BROWN: Okay. Andrew, if you would like to proceed.

MR. NACK: All right. I will do that. Yeah, so as I already mentioned, we've got quite a few slides. NEI went into this thinking that we wanted to provide a more complete overview of the document.

So there's probably going to be sections that we can move through a little bit faster on the conversations that have already happened and what the NRC staff has already covered in their presentation. So I'll try to move through these as quickly as possible. But definitely feel free to stop me and ask questions as we go.

CHAIRMAN BROWN: Don't worry about the extra slides. Better to have what you want than to be asked. So we have no hesitation to ask questions. So I think you know it's not going to be a problem if we do. Okay. Go ahead.

MR. NACK: Sounds good. All right. So just for a quick overall purpose, I'll just go over the purpose of this document is to facilitate commercial-grade dedication process for digital equipment by crediting SIL certification by the accreditation and the NRC approved certification bodies in lieu of the commercial-grade survey and critical design or digital review. So we'll get into a little bit more of what that means as we go through here.

So here's the table of contents. It's just showing out how our presentation and how to walk through the document. So jumping straight into

Section 1 for the introduction, this section as you'd expect is just trying to make sure the reader is oriented on the purpose and scope of the document.

Make sure they understand some of the basic items that need to be accounted for as they're moving in to understanding how this guidance may be applicable to what they're doing and what they're involved in. So Section 1 is where we start getting into describing the safety integrity level concepts. And we've got subtopics of describing the SIL certification process as well as getting into describing what these dependability critical characteristics are that we've talked about quite a bit today.

So with a very high level view of the safety integrity levels, the IEC 61508 standard provides a basic foundation for safety systems that's based on a systematic integrity, probabilistic reliability, and a hardware fault tolerance. So the aspect that we're going to focus on for this guidance is the systematic integrity. The certifications for these products are intended to cover all three of these particular aspects.

But in terms of addressing the applicable parts for the dependability critical characteristics, the systematic integrity is really the important part

for what we're looking at here. So then for the certification process, part of what makes this potentially so useful to the industry is that manufacturers are actually seeking to design and manufacture products in compliance with IEC 61508. And that causes them to create different artifacts during that process that can be used as evidence for the certifying body and the end users to be able to see and review to understand what went into the manufacturer's efforts to ensure safe and reliable operation of the products.

And so a manufacturer after seeking to be in compliance with the standard and assess if they've been successful or not. And sometimes that can be an iterative process where the certifying body may identify some issues. The manufacture has the opportunity to go back and try to address those and strengthen those to re-engage with the certifying body to try again to reach a successful certification process.

Then Section 3 of the EPRI guidance provides an overview of the EPRI research that is a really helpful source of information for discussing the whole IEC 61508 ecosystem, all the different aspects to that. And within this section of the NEI

document, we break it down into a scope, summary, and conclusions. For a deeper understanding of how the IEC 61508 ecosystem works for other industries such as oil and gas or chemical or any of the types that had been discussed earlier, that EPRI research is really helpful resource for that.

So for the sake of what we're discussing here today, I'm just going to focus on the conclusions that were helpful for the NEI team in developing this guidance. So the first conclusion from that research was that the SIL certification aligned well with EPRI TR-106439. This was an important one since as discussed 106439 is already in use and has already been endorsed.

And so this table here just shows some threads, some commonalities between what you would see in a commercial-grade dedication that was utilizing the TR-106439 methodology with what you would find within a safety case for a SIL certification. The next conclusion was that the certifying bodies had to standardize a rigorous and reliable evaluation process. Exida is the major certifying body for the U.S. and TUV Rheinland is a major certifier based in Germany.

Then the next conclusion was the

accreditation bodies ensure that CBs are consistent and trustworthy. So DAkkS is the accreditation body for Germany. And so they cover TUV Rheinland and there's some other TUV entities as well that they cover. And ANAB is, as discussed earlier, the ANCI National Accreditation Board provides the accreditation for Exida here in the U.S. So these next conclusions here are talking about failure data indicating reliable operation of SIL certified equipment.

And the SIL certifications are an accurate indicate of reliability and were very helpful conclusions from this report. EPRI gathered well over a billion hours of operating experience of SIL certified equipment and was able to confirm that the failure rates and the reliability for the majority of cases except for one that is a special case discussed in the report. The failure rates in the certifications were conservative in terms of how those products actually performed in the real world.

And the one exception was actually it turned into an opportunity where the review of the failure rate data was able to help the manufacturer identify some systematic issues within their manufacturing process that was able to be resolved to bring the failure rates back into what was expected

in terms of random failures for the particular SIL level that they were shooting for. And so within the structure just as an example, the certifications issued by Exida assembly you see, the lower left part of the screen is what you'd see on a certificate where it's talking about the capability of the product. Within this certificate, you'd expect it to also identify that it's accredited by ANAB in the case of (audio interference), which ANAB is also a member of the IAF, the International Accreditation Forum, which is an entity that ties the national accreditation boards together.

MEMBER DIMITRIJEVIC: This is Vesna Dimitrijevic. I just have curiosity question. Do you have data for non-certified?

MR. NACK: Do we have data for uncertified products?

MEMBER DIMITRIJEVIC: Yeah.

MR. NACK: Is that what you asked?

MEMBER DIMITRIJEVIC: Yes. It's interesting to compare the data, certified versus the ones which are no certified.

MR. NACK: Right. Yeah, that was not something that EPRI's research covered. It was focused on identifying -- basically, they're saying,

hey, we're interested in really utilizing the SIL certification. What can we do to actually show that this certification actually gives us an indication that we can depend on that these products are going to be reliable? So failure rates weren't gathered for uncertified equipment just because that wasn't part of what the research was going for. So are you saying in terms of you'd be interested to see typical failure rates of uncertified equipment?

MEMBER DIMITRIJEVIC: Yeah, definitely. I mean, from the PRA prospective, that would be very interesting data to compare because we don't really know how to compare -- well, to estimate on the reliability of the -- safety-related to non-safety-related equipment. So it will be very interesting data.

I was just curious. I know it's not part of your research. You just want to be sure they reach your reliability goal. But I was just curious. Thanks.

MEMBER BIER: If I can reply to that, this is Vicki Bier. I think one of the issues is that non-certified equipment is not necessarily less reliable. But there is less assurance of reliability. So you might have great performance on uncertified

equipment from the last ten years. And in the next year, it could become terrible because it's not held to the same kind of standard, so --

MR. NACK: Yeah, that's a good point. Another aspect I was going to add was that the gathering of data is yet another benefit of using manufacturers that are striving to be in compliance with IEC 61508. Manufacturers of uncertified equipment that aren't focused on meeting those same requirements aren't driven to gather and collect the data in the same way that these manufacturers striving for that certification are.

So it (audio interference) operating experience on certified products than it would be for uncertified products. All right. So that brings us to Section 4 of the guidance where we start getting into the actual process for utilizing the SIL certifications. And it's broken down into these four subtopics that we'll jump into here.

So Step 1 basically in utilizing this methodology is that you're identifying the requirements of your application. This would involve figuring out, okay, out of the particular SIL levels, which level is appropriate for your application? And identifying many of the other requirements such as what

are the seismic requirements or EMI or all those things?

The next part of that is that you're confirming that the SIL certification of the equipment that you're choosing encompasses what those requirements of the application are. Then you're going to walk through the process of identifying your critical characteristics for the equipment. And that's where we've talked about that there's three types.

You're going to have your dependability, your performance, and your physical critical characteristics. Then you're doing an evaluation of the CB service to be able to identify the critical characteristics for that service that the CB is providing that we're taking credit for when we're utilizing the certification. Then we're looking to confirm that the CBs accreditation includes IEC 61508.

It's kind of a no-brainer. But it's something that's set as a checkmark that you need to confirm that's going to be one of those important aspects of making sure you've got a valid certificate for what you're trying to accomplish. Then you go into completing that commercial-grade dedication of the CB service.

Part of completing that CGD is the

observations performed by the licensee or their designee that's what was discussed as happening every three years. So this CGD of the CB service doesn't necessarily involve an observation of the AB and the CB every time. But it's taking credit for a successful observation that's occurred within that three-year window.

And you're able to use that to complete that dedication. And completing that dedication is what then makes the SIL certificate reliable in that you can take credit for that within the commercial-grade dedication of the product. And that's the next step is that you're using the certification to address the dependability critical care characteristics of the item.

And then the final step, you still have your performance and physical critical characteristics that you're going to be able to evaluate for acceptability using the traditional methods that are covered in the EPRI 56.52 documents that were discussed earlier. Typically, that's going to be a situation where you can use Method 1 testing to be able to confirm acceptability of those critical characteristics. Then Section 4.2 of the document gives some framework for how to go about determining what the appropriate

SIL level is for an application.

It's built on framework from EPRI TR-106439 that discussing a little bit loosely the ability to utilize a graded approached based on the safety significance and the complexity of the application. So there's potential ways to go about this involving using the PRA. And there are methodologies that are prescribed -- or not prescribed, but identified in IEC 61508 for being able to identify what the appropriate risk level is the equipment needs to be able to address.

In the EPRI HAZCATS (phonetic) methodology is something coming along that also fits nicely into this to be able to determine an appropriate SIL level for the application. And that brings us to 4.3. Within 4.3, we're looking at, okay, you're going to pick equipment that has the capabilities and the functionality that you need for your application.

But then once you're looking at that specific equipment, this section gives you some guidelines to review to make sure you're going to be able to use this methodology involving the SIL certification as part of the dedication. And so you're going to gather your information, the SIL certificate, and the safety manual. You're going to review it,

confirm its validity.

You're going to confirm that it's to the standards that are involved here with IEC 61508. And you're going to proceed to confirm that the systematic capability identified on the certification meets or exceeds the requirements of the application. Then move into making sure that the CB is accredited by an organization that's a part of the International Accreditation Forum.

That's the entity we discussed earlier that links the different national accreditation boards together. Then you'll confirm that the -- so the SIL certificate and the safety manual will provide information about what the safety function is that's been certified. So this Step 4.3.6 is confirming that the safety function for the intended application is encompassed by what this product was certified to be able to perform.

Then in 4.4, we get into the technical evaluation and acceptance methods. If you're familiar with EPRI TR-106439, the first two columns here come straight from that document. And they're really intended to show the different contributions of the manufacturers and the utilities in achieving an adequate level of assurance that a product is going

to perform as required.

So the first column being nuclear grade is a situation where you've got a vendor that's seeking out to design and build products that are in compliance with the nuclear standards and the nuclear quality assurance programs. And the middle column is showing how the utilities and the dedicators are having to compensate for vendors that were not complying with those nuclear standards. So then we've added this third column to show that this SIL certified products provide interactions with manufacturers that are contributing much more in terms of helping to ensure the products are going to have the appropriate level assurance that they're going to perform adequately.

And this is just a visual illustration of the process here. So this is what a EPRI TR-106439 methodology would traditionally look like. And over on the right side of the screen where it says guidance from EPRI 3002002982, that document is the Revision 1 of EPRI NP-5652 that's been discussed earlier.

EPRI just needed to use a different number just the way the process is working. So the left side of the screen is not really what you consider the commercial-grade dedication process. But it's the seismic testing. It's the design review. It's the

EMC testing.

It's making sure the design of the product is going to be adequate for the application. Then on the right side of the screen is the steps you would typically see for a commercial-grade dedication following those EPRI documents. So now with this NEI 17-06 guidance, the SIL certification is able to be used to address the design review within the equipment qualification phase as well as the Methods 2 and 4 of the commercial-grade dedication process which Methods 2 and 4 are specifically identified just because those are traditionally what were used to address the dependability critical characteristics.

So Method 1 traditionally has been how -- or currently is how the performance and the physical critical characteristics are typically evaluated. And then going through that process is how you reach the basic component status or the dedicated commercial-grade component. And I just covered this a little bit of how the -- and this links back to the conclusions of the EPRI research that the CB certification process paralleled pretty consistently with what was traditionally covered with the EPRI Methods 2 and 4 of the commercial-grade survey and looking at the operating experience.

Then we'll just note that Appendix C provides a mapping of the EPRI TR-106439 to the IEC 61508. So as the subcommittee looks into a better understanding of IEC 61508, I would just say it is a rather extensive document. So part of the appendices of the NEI guidance are intended to help narrow in the focus on particular aspects that were important to maintain those dependability critical characteristic concepts from the EPRI TR-106439 document. Then that last note is just what I already said earlier about Method 1 typically being how the physical and performance characteristics are evaluated.

CHAIRMAN BROWN: This is Charlie Brown. Could you hold on a minute?

MR. NACK: Sure.

CHAIRMAN BROWN: We're at 27. Could you flip back to 21?

MR. NACK: Yeah.

CHAIRMAN BROWN: And I've got the 17-06 open to 4.2. As part of determination of the SIL for end users application, about two-thirds of the way down it talks about the design would quantify the required risk factor reduction needed for a specific safety function such as using existing PRA results and then select the SIL digital components and systems that

would meet the requirements to maintain or improve the PRA results. I struggle a little bit with that trying to figure out how somebody is going to select piece parts of a digital design to somehow be ranked into a PRA that doesn't deal with detailed parts within a module or within a drawer or a cabinet.

I've struggled a little bit with how in the world that would even be applied. I mean, it implies you do a PRA of some kind and then figure out you've got a risk factor. And then you're going to design or you're going to do this SIL probability criteria evaluation to see if you could even meet it. I'm not sure I'm even saying this right. I just don't understand how the PRA can part of this process.

(Simultaneous speaking.)

CHAIRMAN BROWN: Is Section 4.2 the next to last sentence -- the third to last sentence rather?

MR. NACK: Looks like Warren may have something to add here. Do you --

MR. ODESS-GILLETT: Yeah.

MR. NACK: -- like to jump in, Warren?

MR. ODESS-GILLETT: Thank you, Andy. Yeah, so what you do is you look at your applications. So let's say it is a system of some sort, whether it's reactor protection, ESFAS, a post-accident monitoring

system. You do look at the PRA for the application in which the product is going to be used in. And then that can give you insights on, well, what should the SIL certification of the product in which that system is going to rely on will need to match up?

CHAIRMAN BROWN: Yeah. I mean, if I look at a reactor trip or say a safeguard system, it's supposed to work. I'm not sure -- normally when you do a PRA, you don't assume the whole thing breaks since it's a multi-channel and all the little lines that they come up with for failures. I guess I just kind of had a hard time figuring how anybody would factor that back into the design and say, hey, look within that system and what are the piece parts because the data you'll have on, say, a circuit card or a component on a circuit card as opposed to just looking at the overall failure from a defense-in-depth standpoint which is typically done with those types of systems.

MR. ODESS-GILLETT: So the PRA usually has input from the reliability analysis of the system that's -- of the system. So normally a reliability analysis is done. And then that reliability number is then fed into the PRA to inform the PRA on the probability risk of not performing its function.

That's how you get the CDF and LERF. So

based on that, you get a sense of how important that system is in contributing to CDF and LERF. And then you match up the SIL to that level.

MEMBER BIER: Yeah, one additional comment. This is Vicki Bier. I hope this is helpful, Charlie. In some cases, those kinds of things would be reflected in the PRA retroactive.

So when I put in a different type of component is as you said it's a tiny piece part of a larger system, I may not know upfront what the effect is on the reliability of that system. But if it starts failing a routine test or does better performance on routine tests with fewer failures, then eventually that will be reflected. But I don't know if that gets at your question.

MEMBER DIMITRIJEVIC: And the other thing I wanted to add, Charlie, when they talk about risk reduction factor, that means they will assume that things perform perfectly. It could be on system levels. So the thing is this system performs perfectly, what would be total improvement in the risk. And based on that, you can actually conclude how much effort it's worth to improve the components of that system because in this system contribution to overall risk is small.

That will say that it's not really important to improve performance. Risk reduction means assuming failure equal to zero and see what is the total impact on the risk. That helps a little?

CHAIRMAN BROWN: Oh, well. I've designed so many systems and delivered so many that -- and normally, I've always had multiple channels of this, that. And I always assume -- we never did a -- when we did our Level 1 PRAs, we would assume that one channel failed or when we had a four channel system. If we only had a two channel system, we never assumed both failed.

I didn't see what I would change to bring that probability of both of them failing back up to none failing or something like that. That's the way I was viewing the reading is how would you use that assessment because when you go back and look at the interior of what's involved, piece parts for a circuit board, for example, you don't have data on the integrated circuit, per se, that you can go do something with. I mean, you have integrated circuit fails.

But go drive back and try to find a world of assessment of that specific integrated circuit. And it's very difficult to do. So I mean, we just put in a new integrated circuit and we go on with our

business.

So that's why I was trying to figure out how the risk factor and the PRM -- not against it. It's just I didn't know how it would apply to the safety systems that we typically operate with. I can see that if you've got a single control function reactivity control where you need to insert stuff.

And if you had no independence of what it took, for example, two circuit breakers to scram as opposed to just one fails. If they're in series, then your system doesn't work very well. In parallel, they don't work very well. I'm just trying to associate it with real hardware that I'm familiar with.

I'll stop right there. We can go on. I just thought I'd ask the question to see if there was a simple answer, and it's a little bit more complex from a PRA standpoint since I'm not real familiar with all that stuff. I appreciate your all's input, Vesna and Vicki. I see Dinesh is holding his hand up.

MR. TANEJA: Yeah, Charlie, if I may give an example. I know we had this discussion during the IP work quite a bit. So one example is that the control room HVAC in most of these reactors that we have operating right now are classified as safety related.

But the risk of failing the HVAC can easily

be mitigated by a number of ways. So do I need to spend a lot of effort in trying to make that highly reliable? Or do I have to make the control system part of that HVAC good enough? Because what we were dealing with is that you have a higher probability of failing the mechanical side of the chillers before you could really fail the control side of it.

So for that example, now do I need to really have a super duper protection system or digital control system? Or can I leave it not so much? So that's where the determination of how you go about selecting what SIL level may be appropriate for that given application. It's just an example of what we consider safety related doesn't necessarily has to be at the level of protection system or ESFAS.

CHAIRMAN BROWN: Forgot to turn off my mic. I listened. I heard you. I understand what you're saying. Just a question. I forgot to ask it as we went through the slides. So I apologize for slowing things down here. Andrew, you can go ahead and go on back to Slide 27.

MR. NACK: All right. Good discussion. Thank you. Yeah, so I think we're done with 27. So now we're moving on to Section 5. This is getting into the evaluation of the accreditation process.

This may be a section where we've already talked quite a bit earlier. But I'll go through it and just let me know if I need to jump ahead. So this Section 5 was divided into the subtopics.

As discussed, the accreditation was really compared to what would be done currently under a commercial-grade survey. So that's just a quick description of how the evaluation was structured. So jumping into 5.2, it was looking -- taking a closer look at the comparison of what the accreditation body covers when they're evaluating the certifying body for compliance with 17065, how that would compare to what would be done by the nuclear industry through the conduct of a commercial-grade survey. So there's pretty good coverage by the ISO 17065.

But as discussed earlier, it were seen as a potential gap related to how the accreditation -- if the level of rigor by the AB was sufficient in terms of verifying the CB scheme was in compliance with the requirements of IEC 61508 which was more of a technical situation more than what you think of as typical quality assurance requirements. So to evaluate the CBs and the accreditation of the CBs with that in mind, we ended up with two different paths for evaluating the CBs. The first one being accreditation only and the next

one being accreditation plus a scheme-specific evaluation to potentially address that gap.

So the accreditation only pathway included this set of criteria for being able for being accomplished and that the AB would be a member of the IAF and MLA which is the multilateral agreement. Then the observers of the AB would be confirming satisfactorily that the AB's assessors had sufficient knowledge of 17065 and that they also had the appropriate level of rigor applied to evaluating the CBs. Then there was looking at the scheme -- the CB scheme and a similar set of criteria for that, that the AB's assessors would be knowledgeable and experienced with IEC 61508 and that they would apply sufficient rigor to evaluate the CB scheme.

Then number 4, it would be performing observations or evaluations of the AB to confirm that they implement adequate measures to manage the accreditation of CBs over a periodic timeframe. So just looking at that they're maintaining the health of their accreditations on a timely basis, over a period of time, looking at, okay, when do we need to go back and reevaluate a CB's accreditation. Then the main difference with the accreditation plus scheme evaluation is that it would involve the observers, the

licensee, or the designee engaging directly with the CB to take a look at their scheme.

This came about from the observations that were discussed earlier with concerns about how deeply ANAB was diving into Exida's scheme covering IEC 61508. So this approach includes this supplemental activity. It's the checklist Appendix D that provides the observers an opportunity to engage with a CB directly to confirm the sufficientness of their scheme.

CHAIRMAN BROWN: Andrew, go back.

MR. NACK: Yeah.

CHAIRMAN BROWN: Is there a requirement for the CBs to periodically get their accreditation re-stamped?

MR. NACK: Yes. So it depends on the particular AB. The situation of ANAB and Exida that we've observed was that ANAB does some type of activity to maintain the accreditation and that's annually. But it's really a two-year cycle of how often the accreditation is updated.

CHAIRMAN BROWN: Does somebody actually audit the accreditation method that the accreditation body is actually doing something other than just making sure people are educated like the comment that was made earlier in terms of how do you ensure that the technical

side of that auditing is -- or re-certification is valid?

MR. NACK: You're asking about who's checking up on the accreditation body?

CHAIRMAN BROWN: Yeah, in a way. I mean, the accreditation body is the one that says, okay, Exida is still doing a good job. Well, how do they confirm that periodically? Is it because of the equipment they've certified and an assessment of certification of that equipment?

The stuff is performing well? Or is it just a procedural or administrative thing to see that they have processes in place that give you that information even though -- or some information on the technical side? Yeah, I'm questioning the accreditation bodies.

MR. NACK: Yeah. So there's multiple layers going on. So on the accreditation body level, I mentioned the international accreditation forum earlier.

CHAIRMAN BROWN: Yes.

MR. NACK: So that's an opportunity for the national accreditation bodies to do peer reviews on each other. So that would be a situation where you have different accreditation bodies looking at each

other's work, making sure they're all maintaining similar levels of rigor and standards. And then down at the CB level is where you have the AB establishing some type of a relationship with the CB.

The AB and the CB have an arrangement for annual or biannual reevaluations that involve audit activities, looking at the process and actually reviewing artifacts of work that's been done. So they'll set up non-disclosure agreements and be able -- the CB will be able to show the accreditation body actual safety cases that they've put together or have reviewed from manufacturers. And so they're looking at the CB's procedures and processes but then also work that's actually been generated by executing those procedures. Is that --

MEMBER BIER: Thank you. This is Vicki Bier again. Following up on Charlie's comment, while I'm not sure there's a magic answer to the problem or question that he raised, I do think it's worth taking seriously because we've seen in other contexts that the accreditation or accountability body can become like captive to the organizations they accredit.

We saw that with the big accounting firms at one point, et cetera. So it's worth some thought about if it's based on physical inspection and

hopefully it's more reliable. But it is a risk, so --

MR. NACK: Yeah, and we'll get into the nuclear -- continuing nuclear oversight later on. But that is why there's that three-year window where the licensee or their designee is required to go observe the ABs and CBs during that process to make sure things are being maintained at a proper level. Do we have some hands up that we need to get to or that people wanted to add?

MR. ODESS-GILLETT: Yeah. Thank you, Andy. This is Warren. And excuse me for the background noise. I've got my window open and somebody is mowing their lawn.

But we don't go to the accreditation only mode until at least an observation has demonstrated that the accreditation body actually does a rigorous audit. And then we don't -- the licensee doesn't need to do this augmented supplemental activity because they can see that it's being done adequately by the CB. And as Andy said, he's going to get into the fact that the Reg Guide is saying that every three years the licensee needs to go back and reassess the rigor.

CHAIRMAN BROWN: I thought going back was just to get his stuff re-certified again, the SIL

re-certified, not necessarily evaluating the certifying body.

MR. ODESS-GILLETT: It's the latter. It's evaluating the rigor of the accrediting bodies accrediting the certifying body every three years.

CHAIRMAN BROWN: Okay. So the guy that's dependent upon the outcome to make sure his stuff is okay is -- has he got enough gumption to -- what he finds out they're not doing well? Now his stuff is no longer still qualified.

MR. ODESS-GILLETT: Well, what our observations are is that they are actually open items in the ANAB audits of Exida. And when they come back the following year, they take those items with them. And they look to see if Exida has closed those open items. But if there is a severe lapse which we don't anticipate based on what our observation is between ANAB and Exida, that would have to be a very short-term relapse because of the frequency of ANAB's accreditation of Exida and then the frequency of the licensee observing that.

MR. NACK: Yeah, there's definitely several different layers to just try to keep track of because there's a periodic review that the CB is performing on the manufacturer, making sure that

they're in compliance with IEC 61508. And you'll see the SIL certificates have validity dates on them from Exida. Before those dates expire, the CB would have to go in and reevaluate the manufacturer's efforts.

Then upper level as we were talking about, there's that relationship between the accreditation of the CB that's on a periodic basis. Then now -- so all that happens outside of the nuclear industry. Then the next thing we get into is, okay, now there's a periodic basis that the nuclear industry is going to come in and observe the ABs and the CBs.

CHAIRMAN BROWN: Who's that?

MR. NACK: So that right now is what we're saying is being performed by the NRC licensee or their designee.

CHAIRMAN BROWN: Yeah, but his incentive is to not -- I'm just looking at incentives. I mean, if he goes and starts, hey, I'm trying to validate that these guys are still doing their job, it's in his best interest not to find a problem.

MR. NACK: Well, not really --

CHAIRMAN BROWN: Potentially, potentially.

MR. NACK: -- because it's really a reputation driven business. And this is an important

aspect to think about the EPRI research and how they gathered the operating experience that was actually able to demonstrate that the SIL certifications were good indicators of reliable performance of the products. So if Exida gets into a situation where the end users are experiencing high failure rates and unreliable behavior of products that the certified, all of a sudden, the end user is going to stop accepting Exida as a valid certification body.

And they're going to say we're only going to use products certified by TUV or something like that. So the incentives for Exida are not driven by successful certifications. I mean, the manufacturers are paying the CBs to evaluate their products regardless of if there's a successful certification.

MR. ODESS-GILLETT: And Andy, this is Warren. I don't know if, Charlie, you're referring to the incentive of the licensee themselves.

CHAIRMAN BROWN: All the way around. I mean --

(Simultaneous speaking.)

MR. ODESS-GILLETT: Okay, yeah. So as far as the --

CHAIRMAN BROWN: That's just the licensee. I mean it's CB and the AB. I mean, you can

always say they might be in bed together and they're always getting certified. And therefore, the licensee is captive at that point and he doesn't know it. So who's detecting it?

You can only have so many layers of backfill trying to figure out if somebody is still doing their job right. Who's checking the checkers that's checking the checkers routine. That was my thought process is these activities have a backstop where they are being checked. And the backstop for the ABs is apparently just more universal accreditation forum that you talked about.

MR. ODESS-GILLETT: But also the backstop could be the nuclear industry itself and its periodic observation of the accreditation process.

CHAIRMAN BROWN: But who is the nuclear industry in this case?

MR. ODESS-GILLETT: Okay. So it's the licensee or designee at the moment. But at some point, we are discussing the possibly of NUPIC taking that role.

CHAIRMAN BROWN: Well, there's a lot of licensees. That's why when you talk about the licensees, every corporation, company, power generating whatever they're called, there's a lot of

licensees.

MR. ODESS-GILLETT: Yeah.

CHAIRMAN BROWN: And how do you -- they're all independent.

MR. ODESS-GILLETT: Yeah.

CHAIRMAN BROWN: So somebody is -- it's hard to see how you walk you way through this minefield.

MR. ODESS-GILLETT: Yeah, and that's --

CHAIRMAN BROWN: That was a problem we had years and years ago with not having a nuclear propulsion examining board back in the naval nuclear program. And we divulged that off to a different -- it used to be done by headquarters. And then once you got so many summaries and aircraft carriers out there, there's only so many of these plants you could go out and do examinations every two years.

MR. ODESS-GILLETT: Yeah, so we're sort of in a chicken and an egg situation here at the moment to implement this because NUPIC is not really interested until the NRC has endorsed this process. But our goal is not to have each NRC licensee going through this process.

CHAIRMAN BROWN: Absolutely not.

MR. ODESS-GILLETT: Right. But we can't say NUPIC is going to do it until this process is

endorsed according to what they're requesting of us.

CHAIRMAN BROWN: What's NUPIC?

MR. ODESS-GILLETT: That's the Nuclear Utility Procurement -- what's the rest of it?

(Simultaneous speaking.)

MR. ODESS-GILLETT: Yeah, thank you, Greg. So it's basically -- it's the licensee -- basically, it's the licensee's designee for doing their supplier audits.

CHAIRMAN BROWN: Okay. Well, okay, now that's a reasonable answer. Okay. If also all the licensees have kind of gotten together if you want to call it that and supporting this operation.

MR. ODESS-GILLETT: Correct.

CHAIRMAN BROWN: Okay.

MS. ANTONESCU: Member Brown, Eric Benner and David Rahn have questions also or raised their hands.

CHAIRMAN BROWN: Okay. Who wants to go fast first? Eric?

MR. BENNER: Well, I'll go first and fast, Member Brown.

CHAIRMAN BROWN: You don't have to go first. Just go first.

MR. BENNER: I think the interesting thing

is you can what if this all day long. And obviously, there's more and more layers. But realize I would say on one level this is better because when you have an Appendix B supplier, the licensee is really relying on that supplier to provide a quality product. Now the licensee obviously still has obligations.

But you rely heavily on that supplier's QA program whereas here as is always the case for commercial-grade dedication, that responsibility does shift to the licensee. Or like we said, hey, on some level if they have an organization that's supporting them. But ultimately the licensees on the hook.

And the idea that there's incentives here to maybe not as faithfully follow the expectations, I say that's in some ways less the case because the licensee is going to be the one who gets a violation if there's a cover up in this process, right? I mean, whereas if there's an Appendix B supplier, it may very well be that supplier that gets the violation. In this case, it is very clear that you as the licensee are going to get the violation if somewhere in this process someone is playing fast and loose with their responsibilities.

CHAIRMAN BROWN: Okay. Somebody else had their hand up?

MR. RAHN: Yes, this is Dave Rahn.

CHAIRMAN BROWN: Okay, Dave. Go ahead.

MR. RAHN: So there's also another backstop. And as part of this process in 61508 is to estimate what the failure of probability is. They usually use it in terms of probability of failure on demand, estimates, and so forth.

But as part of the process, they have to track that in how many failures have actually occurred. And word gets out when a particular product starts failing far in excess of its predicted failure rate. And so ultimately, you can't really hide the fact that a product has been deteriorating.

And the certifying body does this evaluation. But even if he doesn't do that, operating experience in the industry will eventually get to it and point it out. So you really can't hide this forever.

CHAIRMAN BROWN: Okay. All right. Thanks. That was a good discussion. I appreciate your patience with me asking this. I don't really have the plant experience other than my naval experience which was totally different. Interestingly enough. All right. Go ahead, Andrew.

MR. NACK: Okay.

CHAIRMAN BROWN: If there's no more hands

up. I don't see any more hands up.

MR. NACK: It looks like we're all clear.

CHAIRMAN BROWN: Yeah, so go ahead. Thank you.

MR. NACK: Sure. All right. So those were our two approaches. So the next sections -- subsections of Section 5 discuss what we've already been alluding to was our experiences with Exida and ANAB. The accreditation plus scheme evaluation approach was deemed to be necessary.

And NEI and NRC did engage directly with Exida to utilize that supplemental checklist, Appendix D of the NEI document. So an important note here is that I guess it's kind of a demonstration of already this effort having an impact on the accreditation process is that once we identified our issues to ANAB, they have actually taken our supplemental accreditation checklist and embedded it into their process to help address the issues that we raised to them. And so their future accreditation efforts will involve a use of the accreditation -- the supplemental accreditation checklist to make sure their level of rigor of diving into the scheme is adequate.

So now this brings us to Section 6, dedicating entities quality assurance program. And

we've got these five different subtopics within this section. And this section is intended to provide information to the dedicating entity for how to adjust their quality assurance programs that will utilize this methodology.

And that's what 6.1 covers is just talking about the dedicating entities QA program is the target of this section. So then in 6.2, you've got a couple of requirements identified that are needed to be embedded into the procurement process to make sure the equipment is procured in a manner that meets this methodology. So you're going to make sure that you're buying equipment that's certified in a manner that meets the requirements of the application in terms of is it SIL 1, SIL 2, SIL 3.

The number needs to be higher or equal to what the requirement of the application is. You're also going to make sure as we talked about earlier that the safety function is encompassed by the certified safety function of the safety function identified within the safety manual provided by the manufacturer. Then the next procurement requirement is that the CB is accredited to ISO 17065, and that is 61508 identified in their scope of accreditation.

Then next procurement requirement is that

you're going to make sure that that CB is accredited by an entity that's a part of that overall entity, the IAF. Then you're going to make sure that the manufacturer is providing the SIL certificate and the safety manual to the purchaser. And then the sixth subtopic here is a specific clause of IEC 61508 that will drive compliance or it will facilitate notification of the end user by the manufacturer any issues identified within their process that could impact safety.

Or I would say this is driving notification to the dedicating entity that supports their responsibilities related to Part 21. Then to close out Section 6, you've got 6.3, .4, and .5 that's talking about steps to make sure you're establishing the necessary evidence and how to collect that evidence. Then the final section just reiterating the Part 21 aspects and responsibilities that the dedicating entity needs to maintain.

Then Section 7, this is where we get into what we were talking about earlier with the oversight of this process by the nuclear industry by the NRC licensee or their designee is the terminology we're using. And so this section is divided into these subtopics where the organization as discussed is we're

hoping to -- it's ultimately the NRC licensees. But the designee that we're hoping to get involved is NUPIC as discussed.

So going back to the diagram that we used earlier, this is trying to illustrate the different levels of accountability and observations and checking. So you've got the nuclear oversight coming in as this additional piece that's taking a look at maintaining reliability of the accreditation certification process. And so 7.2 is where the NEI is monitoring for any changes to IEC 61508 that if there were any revisions to that document in the future, NEI would monitor that and evaluate if it impacts this process in any way and address that if needed.

And 7.3 is where potentially NUPIC comes into play where this would be on the three-year basis. They're utilizing the different pathways for evaluating the ABs and CBs, the accreditation only or the accreditation plus scheme evaluation. As Warren mentioned earlier, accreditation only would be in situations where the ABs have previously demonstrated sufficient level of rigor in their evaluation of those schemes.

And a little snippet from the EPRI research I wanted to highlight here was at the time of this

information gathering, there's really three major CBs that are doing the majority of the certifications. And that's TUV Rheinland, TUV SUD, and Exida. And so one of the aspects that makes this methodology potentially very powerful is that performing these observations of the AB and CBs pave the way to replace hundreds of commercial-grade surveys and critical digital reviews that really through this work have been identified as being redundant effort for what this IEC 61508 ecosystem is already covering.

And so we see that as a significant benefit. And then just drawing some conclusions to -- or comparisons to the NEI 1405 process that NUPIC is already engaged with is that NUPIC already has experience with doing these types of oversight activities of ABs and CBs. ABs and test labs is the situation that would be in 1405 in there.

So we see NUPIC as being set up well to be able to build on their experience in the highlight process, both 1405 to be able to sufficient address oversight of this 17-06 process. And we've talked several times about the three-year period for when these oversight activities would be performed and the checklist that would be used are the ISO 17065 and the Appendix D of this NEI guidance. And that gets us to

the conclusion of the document. So any remaining questions?

CHAIRMAN BROWN: Not necessarily a question. So your conclusion is interesting in that the adoption of this approach to dedicating commercial items, that this is a more efficient process than the current use of commercial-grade surveys. And you'll get rid of that and there'll be a more efficient application of technical resources.

MR. NACK: Yes. Yeah, and it also has the benefit of driving the use of manufacturers who are actually interested in designing building products in compliance with the safety standard which in the traditional process wasn't necessarily the case. So it improves almost like a pre-identification of the quality of the product.

CHAIRMAN BROWN: But it's also in use by not just the nuclear industry but by critical commercial safety interest industries as well. Is that the case?

MR. NACK: Yeah.

MR. ODESS-GILLETT: And Andy, I'd like to add, too -- this is Warren again -- that it also adds a level of standardization of rigor in the commercial dedication process because the traditional TR-106439

process is really qualitatively based and not directly standard based. I mean, they refer to certain I think IEEE standards. But this process really establishes in my opinion a level of standardization of rigor in the dedication process.

MR. NACK: I definitely agree with that. Good point.

CHAIRMAN BROWN: So this -- my other question is I'm presuming that based on you all proceeding with this and cooperation with the NRC and the back and forth trying to make sure this adopted everybody's insights early as opposed to later and that the number of different licensees around the country, do you think they're onboard with this from that standpoint -- or licensee entities, whatever they are?

MR. NACK: Yeah, I think so. I think they see the benefit of this methodology. And so in the near future, we're engaging -- the NEI team is engaging with those licensees to start getting some pilot projects lined up. Once the NRC has endorsed it, I think we'll have opportunities to put it into practice and demonstrate its value.

CHAIRMAN BROWN: Ever since I got on the committee, I've just been amazed at the dearth of licensees that have not upgraded their reactor trip

and safeguard system to the digital computer-based or FTGA, whatever you want to say it. Would this process make the overall adoption and upgrading of their systems more cost effective?

MR. NACK: I believe it would.

CHAIRMAN BROWN: Is there anybody that's even assessed that as to how that might happen? Warren, you're close to this. You're not saying anything.

MR. ODESS-GILLETT: Yeah, I'm thinking about what you're asking, Charlie, because a lot of licensees are really looking toward NRC approved platforms before even considering them a reactor trip or ESFAS system. But I'd say going forward into the future as new platforms come into the market that certainly having this process will facilitate even the NRC review process.

CHAIRMAN BROWN: Well, it's interesting. The Common Q just pick on one that you're familiar with is already in use for two projects or proposed for two projects. And it would seem to me that once a couple of them were in place that people would be pointing at them.

It's just that just haven't seen much. This stuff is such an upgrade in terms of system

performance, reliability of instrumentation. On top of that, no drift, tighter tolerances, improved margins even in analyses that I just don't understand all the impediments that seem to be in the way of getting there.

MR. ODESS-GILLETT: Well, I think --

CHAIRMAN BROWN: I was hoping this process would help alleviate some of that.

MR. ODESS-GILLETT: Well, I think that this process is very -- a low level process. And really I think industry is looking very closely at Limerick and Turkey Point to see how successful those two projects go. And if they go well, then I think industry is going to hop on board and do their -- the other licensees will start hopping on board. If they start going south, it's just going to be another impediment.

DR. BLEY: Let me ask you another question. This discussion just piqued my interest a little bit. Probably the best way to ensure dependability in software systems is having simplicity. And we've not come from that direction. I think it's primarily because these -- I'll call them big box systems like you've been discussing have a lot more features because they're used other places in the industry. Is there anything about this that might help some folks deliver simpler systems to the nuclear power

plants?

MR. TANEJA: So this is Dinesh. What I might add that the manufacturers that are seeking SIL certification are seeking it on the system that they have designed specifically for safety applications. So those systems that they are designing, it's to their advantage to keep them simple for them to meet all the requirements of IEC 61508.

And the other thing that I might add to the previous discussion is that right now the industry is really looking at the NRC approved platform. They're thinking about doing any digital upgrades. So any future platform that the NRC might review because we as part of our review, we do look at the commercial-grade dedication activities of that platform. So if the platform comes in, in front of us for our review as a topical report, we probably would look at this SIL certified component a little bit differently, right? So that should streamline our work as well when it comes to that.

(Simultaneous speaking.)

DR. BLEY: Down sides? Nobody has spoken of down sides. And we've raised a couple of issues earlier. But I think you've covered those pretty well. Well, wait, maybe there'll be some comments at the

end that touch in that area.

MR. NACK: Yeah, the thing I was going to add was just say I would expect initially that this process would probably be -- I would expect pilot projects to maybe be simpler situations, maybe just like utilizing a digital transmitter instead of some old obsolete analog transmitter or something like that that under the previous EPRI TR-106439 process using a digital SIL certified transmitter would still be an extremely ominous activity. But maybe now with this type of process, it becomes much more reasonable. And so that --

MR. ODESS-GILLETT: I agree, Andy. It's from my experience we run away from things like digital sensors knowing the additional effort required in the dedication process.

CHAIRMAN BROWN: A digital sensor?

MR. NACK: Yep.

CHAIRMAN BROWN: I'm trying to -- what did he do, put a semiconductor down on the pipe to measure the temperature? You're really going to go away from RTDs or differential pressure detectors? I can understand it you've got to convert something analog into a digital signal somewhere along the line.

MR. NACK: Well, the smart transmitter is

using the same basic type of technology. But like you were talking about a few minutes ago with drift and things like that that a smart transmitter will automatically be doing some type of temperature compensation and self-calibration to maintain the stability of its output that the old analog transmitters just weren't capable of doing.

CHAIRMAN BROWN: You can tell how old fashioned I am. Anything that self calibrates I don't trust. I like control.

MR. NACK: Unless it's SIL certified?

CHAIRMAN BROWN: Not even if it's SIL certified. It's just me. Okay? I'm not saying it wouldn't get through. Just at some level it's like applying AI to stuff that modifies stuff based on what it sees going on which don't ever put me in a car with AI. Okay? I'll go back to a carburetor and my screwdriver. It's just I think it's a different task to bridge a gap from a confidence standpoint in a device that is changing its calibration based on what it's reading.

MR. NACK: Yeah, I'm speaking from the context of my day job is here at the Oak Ridge National Lab. And I interact with the calibration techs that are managing the equipment here on site. And when they

see one of these small transmitters, they check it annually like they're supposed to. But they know it's going to be perfectly on year after year as opposed to some of the older ones that they have to deal with.

CHAIRMAN BROWN: Can you put it in a radiation environment?

MR. NACK: That, of course, gets to be more complicated. There's ways to harden it, and there's ways to put the electronics outside the radiation area. So it depends would be the answer.

CHAIRMAN BROWN: Just a side note of discussion, that's all. Are there any other questions from anybody?

(No response.)

CHAIRMAN BROWN: Yeah, I think I probably ought to go and see if we've got any public comments. I've forgotten all the appropriate language. Is there anybody on the public line that would like to make a comment? What do they have to punch? Was is it, star something?

MEMBER REMPE: Star-6, but if they're on -- yeah, if they're on the line, they can just unmute, Charlie.

CHAIRMAN BROWN: Okay. Are there any public -- anybody have a public comment, please state your

name and your organization and feel free to chime in.

Hearing none, I will go on back one more time, back to the members or anybody else that's in the meeting here. Are there any comments that somebody wants to make before we conclude?

I guess there are none. My expectation is just to wrap up. We'll get the transcript out as quickly as I can or as the organization can do that. That's three or four days or whatever.

And we've run through the items. Dinesh, did you write anything else down other than what we went through this morning? I didn't hear anything from this afternoon that somebody asked for additional information. Am I mistaken in that or not?

MR. TANEJA: I also did not hear anything for the afternoon session.

CHAIRMAN BROWN: Okay. If anybody forgot to say something, feel free to email it. That's within the organization here anyway. Get it to Christina, and we'll take it from there. With that, we finished about an hour early, and I'll wish everybody a good Friday and weekend.

(Whereupon, the above-entitled matter went off the record at 3:00 p.m.)

NEI 17-06, Rev. 1 Overview

21 July 2022- ACRS I&C Subcommittee Meeting

NUCLEAR ENERGY INSTITUTE

NEI 17-06 Rev. 1


NEI TECHNICAL REPORT NEI 17-06, Rev 1

Guidance on Using IEC 61508 SIL Certification to Support the Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Related Applications Revision 1

Prepared by the Nuclear Energy Institute
December 2021

https://www.nrc.gov/docs/ML2133/ML21337A380.pdf

- Issued 12/3/2021 (ML21337A380)
- The purpose of this document is to facilitate the commercial grade dedication process for digital equipment by crediting SIL certification by an accredited and NRC-approved certification body in lieu of a commercial grade survey and critical design review

NEI 17-06 Table of Contents

1. Introduction
2. Safety Integrity Level (SIL)
3. EPRI Research of the SIL Certification Process
4. Acceptance of Commercial Grade, SIL Certified, Digital Equipment for Nuclear Safety Applications
5. NEI Evaluation of the Accreditation Process
6. Dedicating Entity's Quality Assurance Program
7. U.S. NRC Licensee Oversight of the SIL Certification Process

Section 1 - Introduction

Section 1 Overview

1.1 Scope

1.2 Purpose

1.3 Pre-Requisites

1.4 Regulatory Basis

1.5 Acceptance of Safety Integrity Level as Verification of Dependability Critical Characteristics

1.6 Acronyms

1.7 References

Section 2 – Safety Integrity Level (SIL)

Section 2 Overview

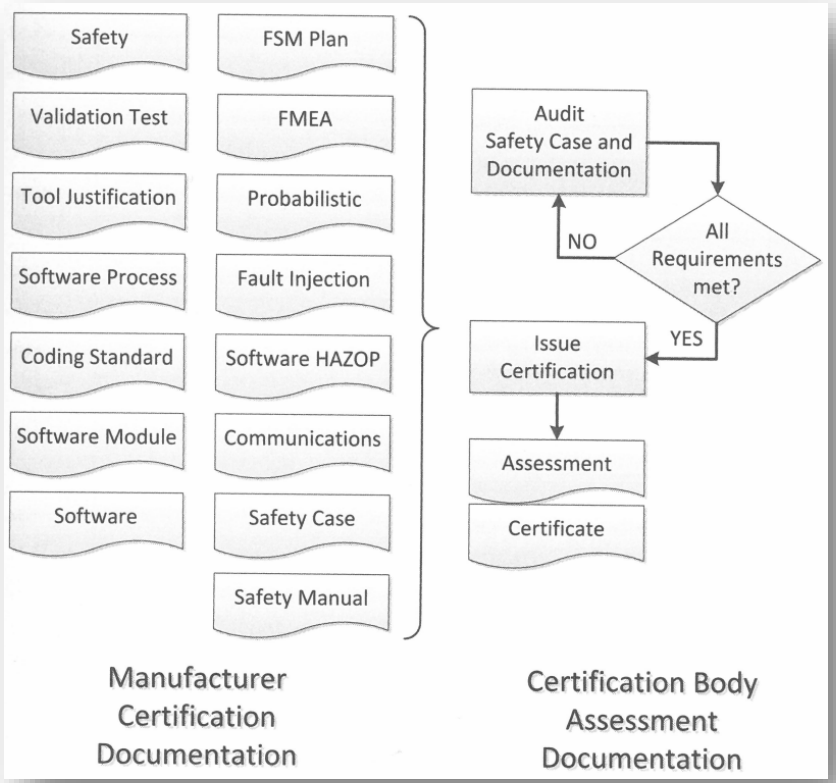
2.1 Description of the Safety Integrity Level (SIL) Certification Process

2.2 Description of the Dependability Critical Characteristics (CCs) per NRC-Endorsed EPRI TR 106439

Safety Integrity Level (SIL) Overview

- SIL Foundation
  - Systematic Integrity
  - Probabilistic Reliability
  - Hardware Fault Tolerance

SIL Certification Process



Section 3 – EPRI Research of the SIL Certification Process

EPRI Research Overview

3.1 Scope of the EPRI Research

3.2 Summary of the EPRI Research

3.3 Conclusion from EPRI Research

3.3 Conclusion from EPRI Research

- SIL certification aligns well with EPRI TR-106439

EPRI TR-106439	SIL Certification- Safety Case
Development Personnel Qualifications/ Experience	
HW/SW Design, Development, Verification & Validation Processes	
Availability/Reliability Requirements	
Failure Modes Analysis/ Testing/ Management	
Design Documentation	
Configuration Management	
Quality Assurance	
SW Requirements Definition & Requirements Traceability	
Vendor Testing (Performance, Environmental, SW V&V, Fault Insertion)	
Product Operating History	
Error Tracking/ Problem Reporting	

3.3 Conclusion from EPRI Research

- Certification Bodies (CBs) have a standardized, rigorous, and reliable evaluation process

- Accreditation Bodies (ABs) ensure CBs are consistent and trustworthy

3.3 Conclusion from EPRI Research

- Failure data indicates reliable operation of SIL certified equipment

- SIL certifications are an accurate indicator of reliability

Section 4 – Acceptance of Commercial Grade, SIL Certified, Digital Equipment for Nuclear Safety Applications

Section 4 Overview

4.1 Application of the SIL Certification Process

4.2 Determination of SIL for End User's Application

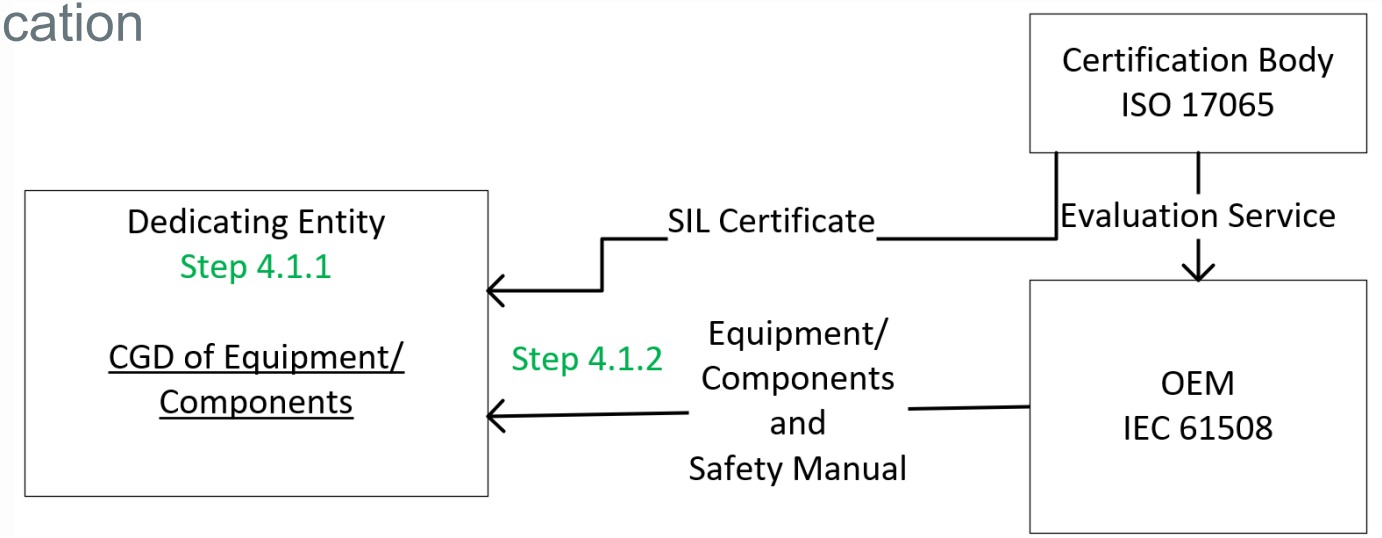
4.3 Selection of SIL Certified Equipment

4.4 Technical Evaluation & Acceptance Method

4.1 Application of the SIL Certification Process

4.1.1 Identify the requirements of the end user's application

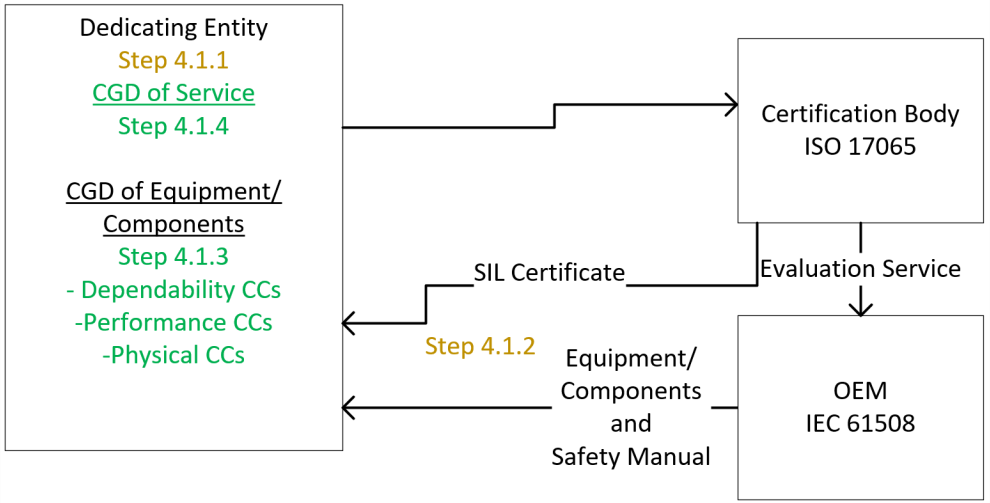
4.1.2 Confirm SIL certification encompasses the requirements of the application



4.1 Application of the SIL Certification Process

4.1.3 Perform a technical evaluation of the equipment to identify critical characteristics

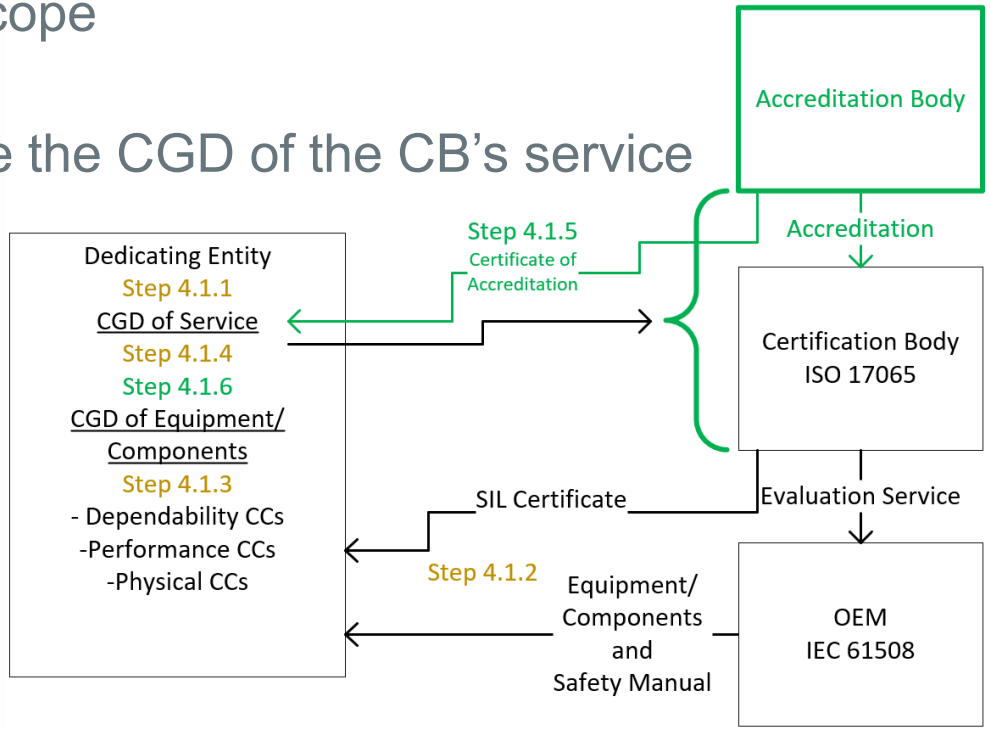
4.1.4 Perform a technical evaluation of the CB's service to identify the critical characteristics of the service



4.1 Application of the SIL Certification Process

4.1.5 Confirm that IEC 61508 certifications are within the CB's accreditation scope

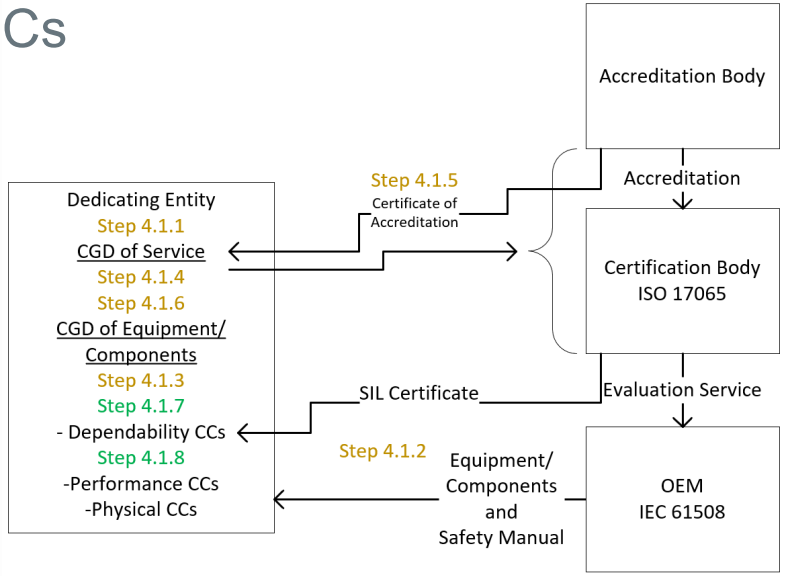
4.1.6 Complete the CGD of the CB's service



4.1 Application of the SIL Certification Process

4.1.7 Use the SIL certification to complete the determination of acceptability of the dependability CCs of the item CGD

4.1.8 Use traditional methods to determine acceptability of the physical and performance CCs



4.2 Determination of SIL for End User's Application

- No specific SIL prescribed, any SIL potentially valid to meet EPRI TR-106439 dependability critical characteristics
- Graded approach (NRC Safety Evaluation Report of EPRI TR-106439)
    - Safety significance
    - Complexity
- Documented engineering judgement for achieving reasonable assurance
    - EPRI HAZCADS is a potential approach

4.3 Selection of SIL Certified Equipment

4.3.1 Obtain the equipment's SIL certificate and the safety manual

4.3.2 Review the certificate and confirm, through the CB, the validity of the certification

4.3.3 Confirm that the certification is to IEC 61508

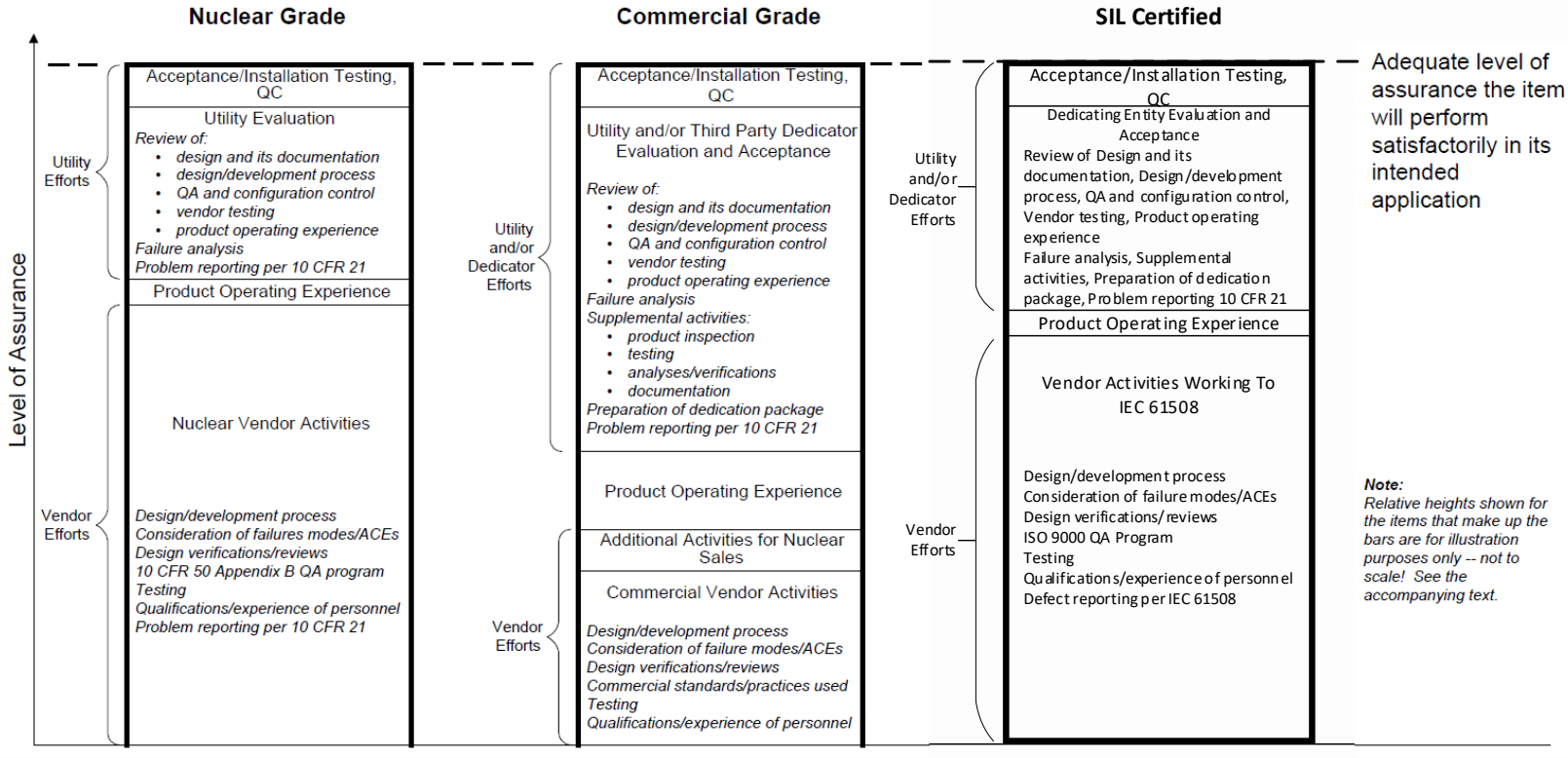
4.3 Selection of SIL Certified Equipment

4.3.4 Confirm that the certified SIL systematic capability meets or exceeds the application requirement

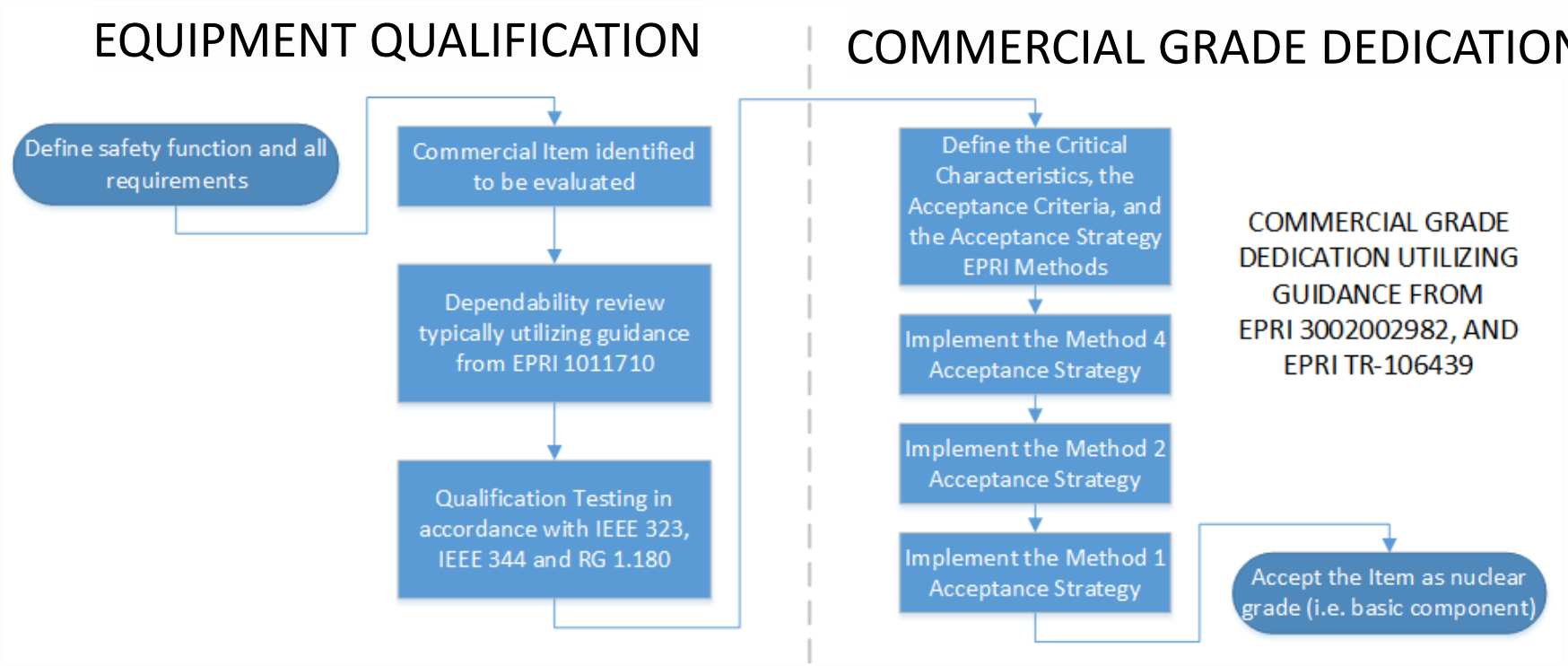
4.3.5 Confirm that the CB is accredited by an organization that is a signatory to the IAF

4.3.6 Confirm that the safety function identified on the certificate and/or in the safety manual encompasses the scope of the safety function of the intended application

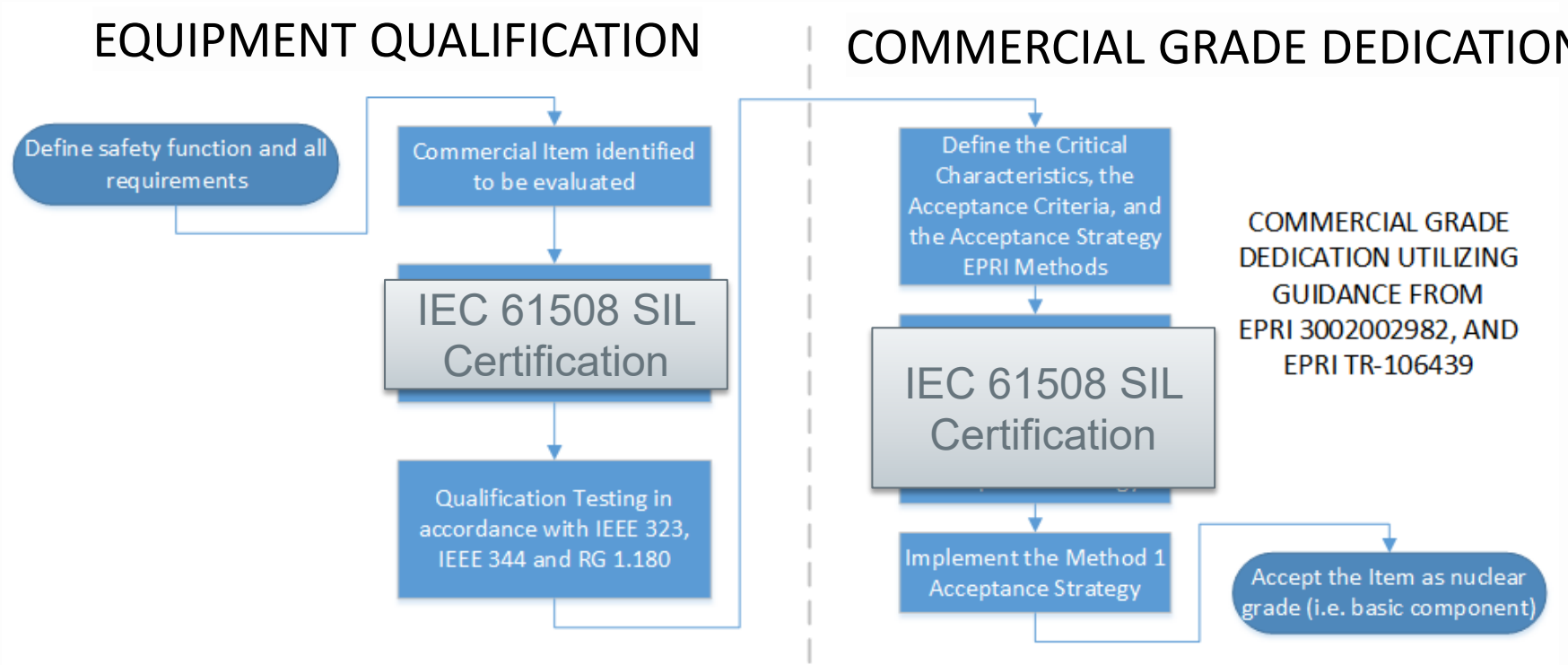
4.4 Technical Evaluation & Acceptance Method



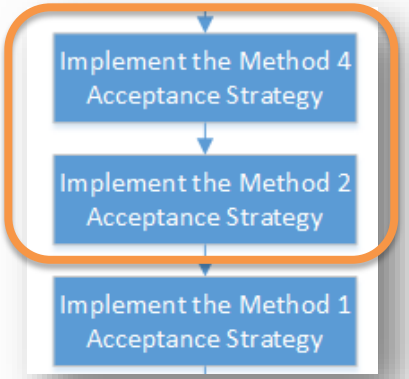
Justification Process- Current



Justification Process- with NEI 17-06



Commercial Grade Dedication- with NEI 17-06



The CB's certification process includes aspects that are equivalent to EPRI Method 2 and Method 4 for dependability CCs

NEI 17-06 Appendix C provides a mapping of EPRI TR-106439 to IEC 61508

The physical and performance CCs are still evaluated using EPRI Method 1 (typically)

Section 5 – NEI Evaluation of the Accreditation Process

Section 5 Overview

5.1 Description of Evaluation

5.2 Result of CGS and Accreditation Comparison

5.3 Paths to Accepting CB Services

5.4 Description of Observation

5.5 Results of Observation

5.6 Initial Use of the Supplemental Accreditation Checklist

5.2 Result of Commercial Grade Survey (CGS) and Accreditation Comparison

- Accreditation to ISO 17065 mostly covered scope of CGS
- Potential for gap identified pertaining to the CB's scheme:

"If the AB demonstrated a sufficient level of rigor to confirm that the CB's scheme did comply with IEC 61508 then there would not be a gap, but if the level of rigor was observed to be lacking then a compensating measure would be needed to be able to complete the CGD of the CB's service."

5.3 Paths to Accepting CB Services

- Accreditation Only
- Accreditation Plus Scheme Evaluation

5.3 Paths to Accepting CB Services – Accreditation Only

1. A U.S. NRC licensee, their designee, or the dedicating entity must confirm that the AB is a signatory of the IAF MLA.
2. A U.S. NRC licensee, their designee, or the dedicating entity performs an observation of the AB as they conduct an ISO 17065 accreditation assessment of a CB. The following characteristics must be satisfactorily observed:
    a. The AB's assessors must be knowledgeable of and have experience with ISO 17065.
    b. The AB's assessment must be of a level of rigor that provides confidence in the conclusions about the CB's compliance with ISO 17065.

5.3 Paths to Accepting CB Services – Accreditation Only

3. A U.S. NRC licensee, their designee, or the dedicating entity performs an observation of the AB as they conduct an assessment of a CB's scheme against the requirements of IEC 61508. The following characteristics must be satisfactorily observed:
    a. The AB's assessors must be knowledgeable of and have experience with IEC 61508.
    b. The AB's assessment must be of a level of rigor that provides confidence in the conclusions about the CB's compliance with IEC 61508.
4. A U.S. NRC licensee, their designee, or the dedicating entity performs an observation or evaluation of the AB to confirm that they implement adequate measures to manage the accreditation of CBs over a periodic timeframe.

5.3 Paths to Accepting CB Services – Accreditation Plus Scheme Evaluation

- Same as “Accreditation Only” except observation of AB’s assessment of the CB’s scheme is replaced with:

  A U.S. NRC licensee, their designee, or the dedicating entity interacts with the CB to complete the supplemental accreditation checklist (included in Appendix D) to confirm that the CB’s scheme meets the relevant requirements of IEC 61508.

Section 5 of NEI 17-06

5.4 Description of Observation

NEI and NRC observed ANAB assessing exida

5.5 Results of Observation

Accreditation Plus Scheme Evaluation was determined to be appropriate

5.6 Initial Use of the Supplemental Accreditation Checklist

NEI and NRC assessed exida's scheme (Appendix D of NEI 17-06)

NOTE: ANAB has incorporated the Supplemental Accreditation Checklist into their accreditation process

Section 6 - Dedicating Entity's Quality Assurance Program

Section 6 Overview

6.1 Organization

6.2 Procurement Document Control

6.3 Tasks Associated with Digital Dependability Evidence

6.4 QA Evidence for Digital Dependability

6.5 Corrective Action

Section 6 of NEI 17-06

6.1 Organization

This process of utilizing SIL certifications must be integrated into the dedicating entity's QA program

6.2 Procurement Document Control

6.2.1 The equipment must be certified to the IEC 61508 SIL that is required by the application, or to a higher SIL

6.2.2 The scope of the SIL certification must encompass the scope of the safety function required by the application

6.2.3 The SIL certification must be issued by a CB that is accredited to ISO 17065 and has IEC 61508 within its scope of accreditation

6.2 Procurement Document Control

6.2.4 The AB of the CB must be a signatory to the International Accreditation Forum (IAF).

6.2.5 The IEC 61508 SIL certificate and safety manual must be deliverables to the purchasing organization.

6.2.6 Clause 7.8.2.2 of IEC 61508 must be imposed. This will require notification of any condition that impacts safety, and this notification will support the dedicating entity's Part 21 reporting responsibility.

Section 6 of NEI 17-06

6.3 Tasks Associated with Digital Dependability Evidence

- Steps to establish dependability evidence

6.4 QA Evidence for Digital Dependability

- Steps to collect evidence

6.5 Corrective Action

- Corrective action program, 10CFR21 responsibility, and contractual relationship with equipment manufacturer

Section 7 – US NRC Licensee Oversight of the SIL Certification Process

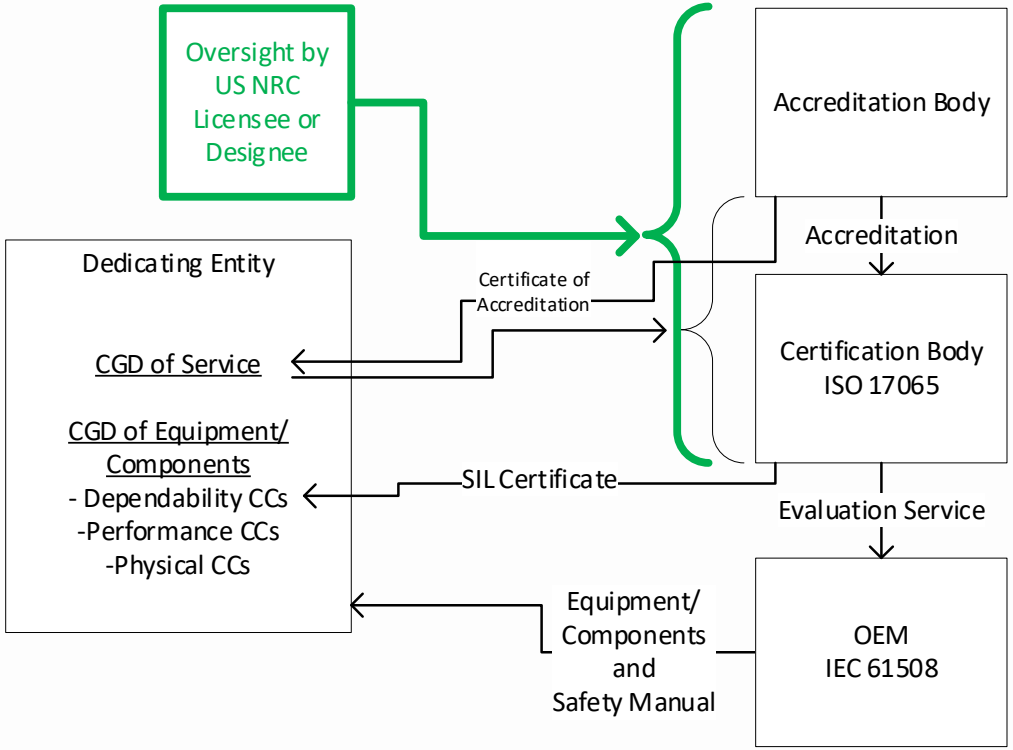
Section 7 Overview

7.1 Organization

7.2 Verification that the SIL Certification Process Continues to be Consistent with NRC Endorsed Practices

7.3 Verification that Implementation of the IEC 61508 SIL Certification Process Continues to be Consistent with NRC Accepted Practices

NEI 17-06 Flow Diagram



Section 7 of NEI 17-06

7.1 Organization

7.2 Verification that the SIL Certification Process Continues to be Consistent with NRC Endorsed Practices

- “As part of the continued oversight, a nuclear industry team, through NEI, will monitor the IEC 61508 SIL certification requirements to verify that they continue to cover the EPRI TR 106439 Dependability Critical Characteristics.”

7.3 IEC 61508 SIL Certification Process Implementation Consistency

- Efforts are in progress to collaborate with NUPIC to conduct future observations of ABs and CBs

- Verifications will utilize the “Accreditation Only” or the “Accreditation plus Scheme Evaluation” approach from section 5 of NEI 17-06

U.S. NRC Licensee Oversight

"As reported by the ARC Advisory Group, for the years 2004-2014, TÜV Rheinland/TÜV SÜD certified 56% (by total revenues) of safety logic solvers, compared with exida's 44%. Over that same period, exida certified 62% (by total revenues) of safety field devices, compared with 38% for the TÜV companies."

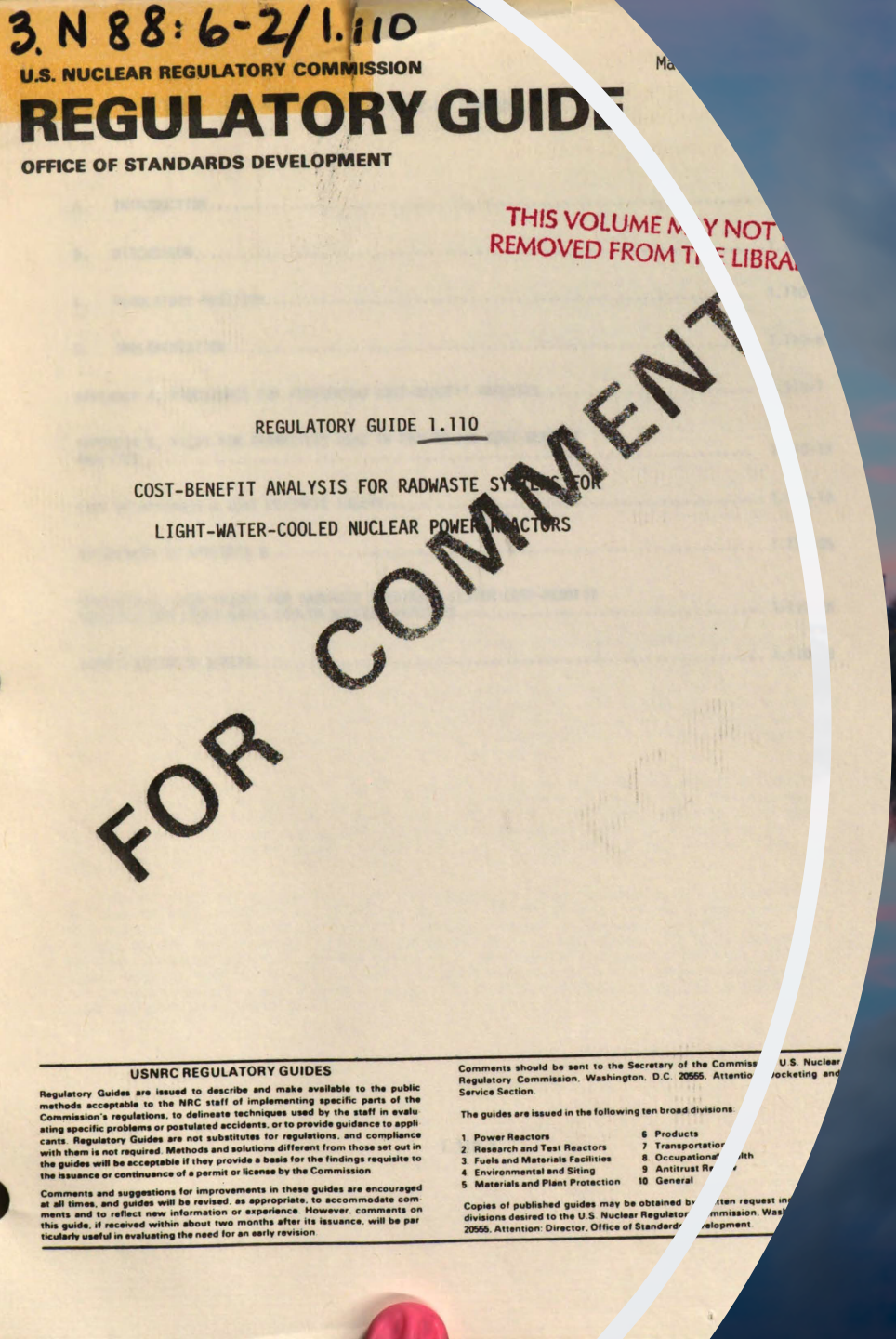
Safety Integrity Level (SIL) Certification Efficacy for Nuclear Power. EPRI, Palo Alto, CA: 2019. 3002011817

Three AB/CB observations will replace the need for **hundreds** of commercial grade surveys and critical digital reviews.

U.S. NRC Licensee Oversight

- Like ILAC Oversight with NEI 14-05
  - Observe ABs' oversight activities of CBs
  - Two ABs and Three CBs currently cover majority of products
- A minimum of every three years (per NRC DG-1402)
  - ANAB/exida needs to be observed 2024
  - TUV is to be determined
- Checklists:
  - ISO 17065
  - NEI 17-06 Appendix D

Questions



Draft Regulatory Guide DG-1402

Proposed new RG 1.250

"Dedication of Commercial-Grade Digital I&C Items for Use in Nuclear Power Plants"

July 21, 2022

ACRS Subcommittee Meeting

Opening Remarks

Eric Benner, Director
Division of Engineering & External Hazards

Office of Nuclear Reactor Regulation

DG-1402 Working Group

Dinesh Taneja, Technical Lead
Sr Electronics Engineer, NRR/DEX/ELTB

- **Michael Eudy –** Project Manager, RES/DE/RGPMB
- **Bernard Dittman** – Sr I&C Engineer (Retired), RES/DE/ICEEB
- **David Rahn –** Sr Electronics Engineer, NRR/DEX/ELTB
- **Greg Galletti –** Sr Rx Ops Engineer, NRR/DRO/IQVB
- **Odunayo Ayegbusi –** Rx Ops Engineer, NRR/DRO/IQVB
- **Jack Zhao** – Sr Electronics Engineer, NRR/DEX/ELTB
- **Jonathan Ortega-Luciano -** (Former) Rx Ops Engineer, NRR/DRO/IQVB

Meeting Topics

- DG-1402 Scope & Purpose
- Background:
  - *CGD of digital equipment*
  - *DI&C Modernization Project (MP) #3*
  - *Development of NEI 17-06*
- DG-1402 Regulatory Basis
- DG-1402 NRC Staff Regulatory Guidance
- Resolution of Public Comments on DG-1402

DG-1402 Scope & Purpose

- Endorse NEI 17-06, Revision 1
- Endorse applicable parts of the industry consensus Std. IEC 61508, 2.0 Edition
- Endorse applicable parts of the industry consensus Std. ISO/IEC 17065:2012
- Describe relationships with existing endorsed CGD guidance documents RG 1.164 and EPRI TR-106439

DG-1402 Background

- EPRI TR-106439 describes an approach for the evaluation and acceptance of commercial-grade digital equipment
- RG 1.164 describes acceptable methods for the dedication of commercial-grade items and services.
- In April 2016 NEI proposed a task under DI&C Integrated Action Plan (IAP) to leverage SIL certification to IEC 61508 in commercial-grade dedication of digital equipment
- Proposed guidance to follow the NRC approved NEI 14-05 process for procuring commercial-grade laboratory calibration and test services

DG-1402 Background (continued)

- In parallel, EPRI initiated a research on SIL certification of digital equipment used in non-nuclear process industry and produced report EPRI 3002011817, “Safety Integrity Level (SIL) Certification Efficacy for Nuclear Power”
- As a part of MP #3 task, NEI initiated developing NEI 17-06 guidance informed by the EPRI research
- The NRC staff provided continual feedback during NEI 17-06 development
- On multiple occasions, the staff observed audits of certifying body (exida, LLC) by the accrediting body (ANAB)
- After resolution of NRC staff comments, NEI 17-06, Rev. 1 was submitted in Dec-2021 for NRC endorsement

DG-1402
Regulatory Basis

- 10 CFR 21.3 defines basic component as, among other things, “commercial grade items which have successfully completed the dedication process” and provides definitions for “commercial grade item” and “dedication”

- 10 CFR Part 50, Appendix B, Criterion III, “Design Control,” and Criterion VII, “Control of Purchased Material, Equipment, and Services,” includes provisions for QA and quality control that are applicable to the acceptance and dedication process for commercial-grade digital I&C items

DG-1402 Staff Regulatory Guidance

Position 1

1. DG-1402 endorses, with clarifications, NEI 17-06, Revision 1, on using IEC 61508 SIL certification to support the acceptance of commercial-grade digital equipment that is dedicated as a basic component in accordance with EPRI TR-106439

DG-1402 Staff Regulatory Guidance

Position 1 clarifications

a. The NRC staff considers SIL certification to be a commercial grade survey for the purposes of Part 21. Thus, considers dedication of the certifying body's services and verification of SIL certification to be adequate for verifying dependability critical characteristics

b. Each dedicating entity should dedicate the services of each certifying body and should not rely on dedication by, e.g., another NRC licensee

DG-1402 Staff Regulatory Guidance

Position 1 clarifications (continued)

c. In keeping with NRC staff-accepted practices, the certifying bodies' SIL certification process should be observed every 3 years

d. In accordance with 10 CFR 21.3, the NRC use of the term "basic component" includes dedicated commercial grade items

e. Dedicating entities should take measures to avoid the acceptance of expired, counterfeit or fraudulent SIL certificates

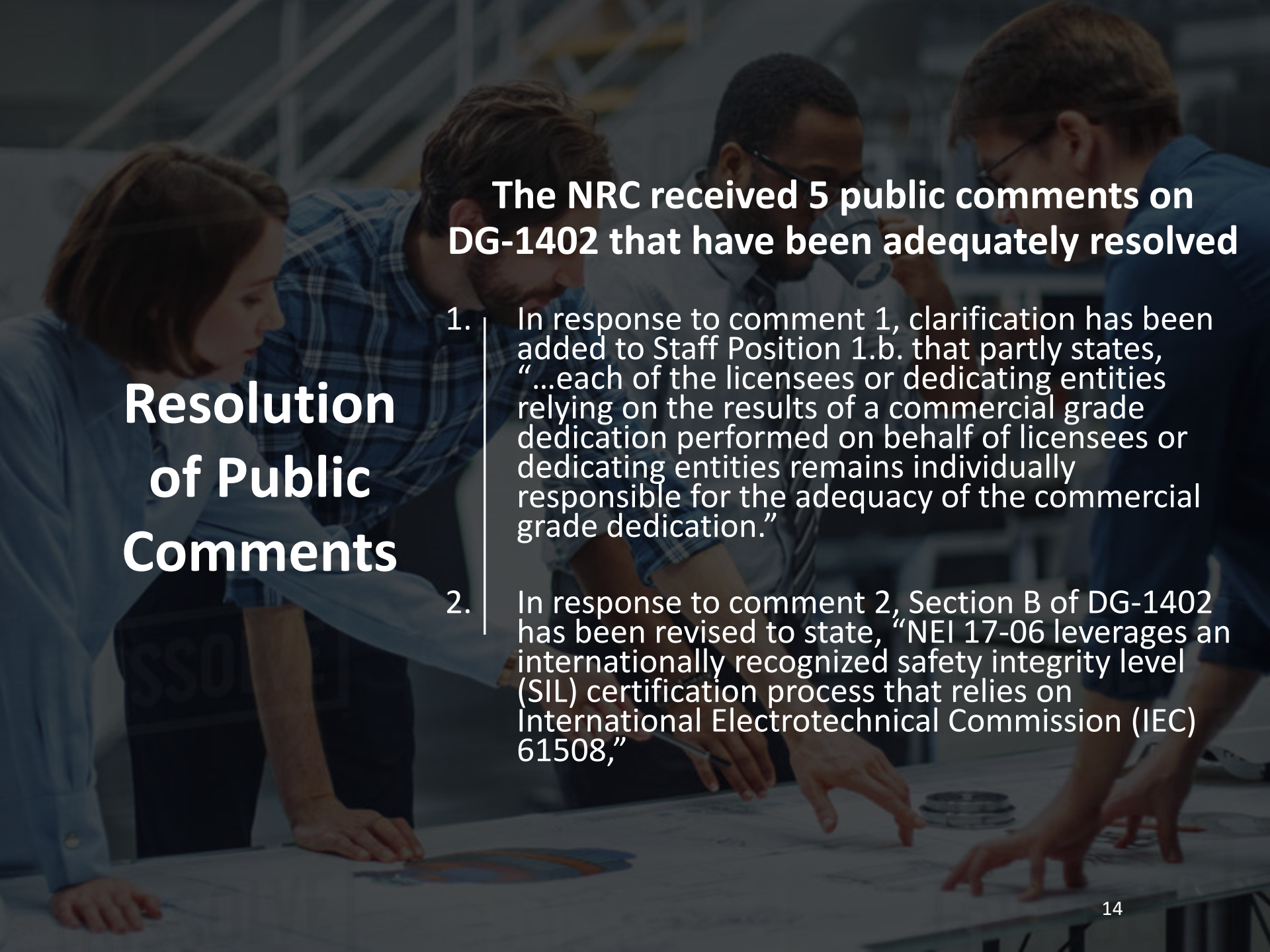
DG-1402 Staff Regulatory Guidance

Position 2 with clarifications

2. DG-1402 endorses, with clarifications, use of IEC 61508, Edition 2.0 as described in NEI 17-06
   a. Dedicating entities should verify the certifying body's accreditation consistent with the guidance in section 6.3 of NEI 17-06
   b. Dedicating entities should verify that the substantive requirements of the later editions related to the dependability characteristics remain unchanged from the IEC 61508, Edition 2.0

DG-1402 Staff Regulatory Guidance
Position 3

3. DG-1402 endorses the use of ISO/IEC 17065:2012 by certifying bodies to perform commercial grade surveys as described in NEI 17-06



Resolution of Public Comments

The NRC received 5 public comments on DG-1402 that have been adequately resolved

1. In response to comment 1, clarification has been added to Staff Position 1.b. that partly states, "…each of the licensees or dedicating entities relying on the results of a commercial grade dedication performed on behalf of licensees or dedicating entities remains individually responsible for the adequacy of the commercial grade dedication."

2. In response to comment 2, Section B of DG-1402 has been revised to state, "NEI 17-06 leverages an internationally recognized safety integrity level (SIL) certification process that relies on International Electrotechnical Commission (IEC) 61508,"

Resolution of Public Comments (continued)

3. NRC staff agrees with comment 3 and the recommended edit has been made to Section B of DG-1402, “The NRC staff considers SIL certification to be a commercial grade survey for the purposes of Part 21.”

4. NRC staff agrees with comment 4, but not entirely with the recommended edits. Staff Position 2.a. has been edited to clearly indicate that NEI 17-06 is leveraging an existing certifying bodies’ accrediting process.

5. NRC staff disagrees with the comment 5 recommendation of a reduced frequency for observing certifying bodies certification process. Therefore, no changes were made to DG-1402 as a result of this comment.

Questions