

# **Official Transcript of Proceedings**

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ADVISORY COMMITTEE ON REACTOR SAFEGUARDS

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UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

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701ST MEETING

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS  
(ACRS)

+ + + + +

TUESDAY

NOVEMBER 29, 2022

+ + + + +

The Advisory Committee met via  
Videoconference, at 1:00 p.m. EST, Joy L. Rempe,  
Chairman, presiding.

COMMITTEE MEMBERS:

JOY L. REMPE, Chairman  
WALTER L. KIRCHNER, Vice Chairman  
RONALD G. BALLINGER, Member  
VICKI M. BIER, Member  
DENNIS BLEY, Member  
CHARLES H. BROWN, JR., Member  
VESNA B. DIMITRIJEVIC, Member  
GREGORY H. HALNON, Member  
JOSE MARCH-LEUBA, Member  
MATTHEW W. SUNSERI, Member

ACRS CONSULTANT:

STEPHEN SCHULTZ

DESIGNATED FEDERAL OFFICIAL:

CHRISTINA ANTONESCU

ALSO PRESENT:

MIKE BALAZIK, NRR/DANU/UNPL

JEFF BARTELME, SHINE Medical Technologies

ERIC BENNER, NRR/DEX

JOSH BORROMEO, NRR/DANU/UNPL

MICHAEL EUDY, RES/DE/RGPMB

CATHERINE KOLB, SHINE Medical Technologies

KIM LAWSON-JENKINS, NSIR/DPCP/CSB

KHOI NGUYEN, NRR/DEX/ELTB

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

PAGE

1) Opening Remarks by the ACRS Chairman (Open)

(JLR/LJB)

1.1) Opening Statement 4

1.2) Agenda and Items of Current Interest 6

2) Draft Guide (DG)-1374, "Criteria for Use of  
Computers in Safety Systems at Nuclear Power Plants"

(Open) (CB/CA)

2.1) Subcommittee Chairman remarks 7

2.2) Presentation and discussions with NRC staff 8

3) Committee Deliberation on DG-1374, "Criteria for  
Use of Computers in Safety Systems at Nuclear Power  
Plants"/Preparation of Reports (Open) (CB/CA)

3.1) Committee Deliberation 69

3.2) Report Preparation 69

4) SHINE Operating License Application -- Final Safety  
Evaluation Report (Open/Closed) (RB/CB)

4.1) Remarks from the Subcommittee Chairman 71

4.2) Presentations and discussion with  
representatives from the NRC staff 72

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

1:00 p.m.

CHAIRMAN REMPE: Okay. It's 1:00 p.m. on the East Coast. This meeting will now come to order. This is the first day of the 701st meeting of the Advisory Committee on Reactor Safeguards.

I'm Joy Rempe, Chairman of the ACRS. Other members in attendance are Ron Ballinger, Charles Brown, Vesna Dimitrijevic, Walt Kirchner, Jose March-Leuba, and Matt Sunseri.

Member Petti has been excused today. Member Halnon is not present at this time, but he will be participating intermittently during this meeting. And Member Bier is having some connection difficulties, but we anticipate that she'll be joining us shortly. Nevertheless, I note we do have a quorum.

Today the committee is meeting in-person and virtually. The ACRS was established by the Atomic Energy Act and it's governed by the Federal Advisory Committee Act.

The ACRS section of the USNRC public website provides information about the history of this committee and documents such as our charter, bylaws, Federal Register notices for meetings, letter reports, and transcripts of all full and subcommittee meetings,

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1 including all slides presented at the open meetings.  
2 The committee provides its advice on safety matters to  
3 the Commission through its publicly available letter  
4 reports.

5 The Federal Register notice announcing  
6 this meeting was published on November 14, 2022. This  
7 announcement provided a meeting agenda, as well as  
8 instructions for interested parties to submit written  
9 comments or request opportunities to address the  
10 committee. The designated federal officer for today's  
11 meeting is Ms. Christina Antonescu.

12 The communications channel has been opened  
13 to allow members of the public to monitor the open  
14 portions of the meeting. The ACRS is now inviting  
15 members of the public to use the MTeams link to view  
16 slides and other discussion materials during these  
17 open sessions. The MTeams link information was  
18 placed in the Federal Register notice and agenda on  
19 the ACRS public website.

20 We received no written comments or  
21 requests to make oral statements from members of the  
22 public regarding today's session. Periodically the  
23 meeting will be opened to accept comments from  
24 participants listening to our meetings. Written  
25 comments may be forwarded to Ms. Christina Antonescu,

1 today's DFO.

2 During today's meeting the committee will  
3 consider the following topics: Draft Guide 1374,  
4 Criteria for Programmable Digital Devices and Safety-  
5 Related Systems of Nuclear Power Plants, and the SHINE  
6 Operating License Application -- Final Safety  
7 Evaluation Report. Note that portions of the SHINE  
8 discussion may be closed, as stated in the agenda.

9 A transcript of the open portions of the  
10 meeting is being kept. It's requested that speakers  
11 identify themselves and speak with sufficient clarity  
12 and volume so they can be readily heard.  
13 Additionally, participants should mute themselves when  
14 not speaking.

15 At this time, I'd like to ask other  
16 members if they have any opening remarks. And I'd  
17 also like to ask whoever has their phone not on mute  
18 to please mute it.

19 COURT REPORTER: That's the court  
20 reporter.

21 CHAIRMAN REMPE: Okay. So if not, I would  
22 then like to ask Charlie Brown to lead us in our first  
23 topic for today's meeting.

24 Charlie?

25 MEMBER BROWN: Okay. Thank you very much,



1 Joy. I don't have any other additional comments to  
2 make. I will just call on Eric and Khoi to make  
3 opening remarks and start on the presentation.

4 MR. BENNER: Okay. Thank you.

5 This is Eric Benner. I'm the Director of  
6 the Division of Engineering and External Hazards,  
7 which has programmatic lead for digital I&C licensing.  
8 We briefed the subcommittee just a few short weeks ago  
9 and found those discussions very fruitful.

10 In the interim time, we reshaped our  
11 presentation today to mostly focus on the things we  
12 heard in the subcommittee meeting such that the staff  
13 and the committee could continue dialoguing on these  
14 issues. We feel that will be most productive to help  
15 the committee in developing their letter report.

16 That being said, we have the presentation  
17 that we used at the subcommittee meeting queued up.  
18 If there are other questions that come up, we  
19 certainly are going to use the time to answer any of  
20 the questions the committee has, whether it was on  
21 topics we heavily discussed at the subcommittee or  
22 anything else that has come up in the interim.

23 With that, I'm going to turn it over to  
24 Khoi, who will be our lead presenter.

25 MR. NGUYEN: Thanks, Eric.

1 My name is Khoi Nguyen. I'm an engineer  
2 from the Engineering Branch in the Division of  
3 Engineering and External Hazards in NRR. I'm here to  
4 present the Draft Guide 1374, the proposed revision of  
5 the Reg Guide 1.152, Criteria for Programmable Digital  
6 Devices in Safety-Related Systems of Nuclear Power  
7 Plants.

8 Next slide, please.

9 As you see and as shown on the slide, the  
10 development of this draft guide involved the staff  
11 from six divisions of the three different offices.

12 Next slide, please.

13 This slide shows the outline of today's  
14 presentation.

15 Next slide, please.

16 The scope of the Draft Guide 1374 is to  
17 endorse IEEE Standard 7-4.3.2-2016 as an acceptable  
18 approach to meet the regulatory requirements for  
19 promoting the high-functional reliability, desired  
20 quality, and secure development and operational  
21 environment for the use of programmable digital  
22 devices in the safety-related systems of nuclear  
23 power-generating stations.

24 For the purpose of this meeting, I would  
25 like to use the term 7-4.3.2 for IEEE Standard 7-4.3.2

1 and the term SDOE for secure development and  
2 operational environment.

3 Next slide, please.

4 This slide shows the major changes in the  
5 standards of the 7-4.3.2-2016 version. It  
6 incorporates the SDOE guidance from Reg Guide 1.152  
7 Revision 3. It provides the specific criteria on the  
8 use of software tools in the digital devices and the  
9 development of hardware, software, firmware, and  
10 programmable logic. It also revised Annex D,  
11 Identification and Control of Hazards.

12 Next slide, please.

13 The proposed change under this revision of  
14 the draft guide to remove the SDOE guidance from Reg  
15 Guide 1.152 Rev 3, that has been incorporated into the  
16 7-4.3.2-2016 version. It endorsed Revision 2016 of 7-  
17 4.3.2 with exceptions and clarifications, including  
18 additional guidance for fault detection and self-  
19 diagnostics if used in digital I&C systems.

20 It provides guidance and clarification for  
21 control of access and endorsement of the Annex D,  
22 Identification and Control of Hazards. Finally, it  
23 includes additional guidance for providing safeguards  
24 for safety-related programmable digital devices before  
25 installation.

1 Next slide, please.

2 CHAIRMAN REMPE: Before you leave that  
3 slide -- again, I apologize for missing the  
4 subcommittee meeting, but I did look over the slides  
5 and the transcript.

6 There were a lot more changes in your  
7 earlier, more in-depth presentation incorporated. And  
8 one of them that I don't see here that was not only in  
9 your earlier slide pack but discussed a lot by the  
10 subcommittee was the fact that you've drawn in some  
11 language from ISG-04 related to independence.

12 During the discussions, the subcommittee  
13 members explored about when you're going to retire  
14 ISG-04. There was a lot of discussion about a need  
15 for a road map and things like that because of the  
16 spaghetti of regulations.

17 And I guess I'd like to explore that a  
18 little here because I noticed you don't even list it  
19 here, and I saw the subsequent slides that you're  
20 going to be going through about the changes and the  
21 comments. That one was not mentioned in today's  
22 package.

23 Why do you not mention that and the fact  
24 that -- it was one of the major points that the  
25 subcommittee emphasized about trying to decide whether

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1 ISG-04 was -- what parts of it were still applicable  
2 or not. Could you elaborate a bit about why you're  
3 not mentioning it today?

4 MR. NGUYEN: There's no particular reason  
5 I didn't include that clarification for ISG-04 in this  
6 presentation. But if you want to know why I didn't  
7 include it, as stated in the slide, this draft guide  
8 endorses the standard with exception and  
9 clarification.

10 It has an inclusive list of details of all  
11 the changes. We endorse the standard with  
12 clarification. And some of them from the ISG-04  
13 didn't incorporate into 7-4.3.2. So in this draft  
14 guide we put the guidance from ISG-04 in the guidance,  
15 but there's no new guidance included.

16 CHAIRMAN REMPE: So one of the points the  
17 subcommittee members made was how does an applicant  
18 know they still need to look at ISG, certain parts of  
19 it that are not brought into this reg guide.

20 I guess I thought that was something that  
21 the staff had kind of agreed, yes, maybe we need a  
22 better road map and we need to identify that ISG still  
23 holds until we can get where we retire it. And then  
24 when I looked at the subcommittee discussion, I never  
25 saw a clear time table when ISG-04 would be retired.

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1 MR. BENNER: This is Eric Benner. We took  
2 it that that discussion was offline from this, that  
3 the bigger picture of the road map to help the  
4 committee understand how all this stuff fits together  
5 was separate from this document.

6 The reality is all of the ISGs are  
7 guidance to the staff. And so they won't get sunset  
8 until that guidance gets incorporated into the formal  
9 staff guidance of the standard review plan. In the  
10 meantime, we also allow licensees to look at staff  
11 guidance to understand where the staff is coming from.

12 So in reality, I believe we really should  
13 have companion guidance in both the guidance to  
14 industry, which is typically in the form of regulatory  
15 guides, and the guidance to staff, which is namely  
16 embodied in the standard review plan.

17 ISG-04 won't, strictly speaking, be  
18 retired until it gets morphed into the standard review  
19 plan. But this is now the guidance we're putting out  
20 to the industry on these topics.

21 CHAIRMAN REMPE: This helps me. You've  
22 got to go and get all of the SRP. But in your  
23 perspective, this discussion about ISG-04, you need to  
24 remind people it should not be put in the reg guide  
25 because it's --

1 MR. BENNER: Correct.

2 CHAIRMAN REMPE: Okay. That helps me  
3 understand your perspective. We'll see what the  
4 committee's perspective is, but yes.

5 MEMBER BROWN: Before he goes on -- this  
6 is Charlie -- that is brought up in the letter, Joy.  
7 So we had our opportunity to address this in one way  
8 or the other.

9 CHAIRMAN REMPE: I'm aware of that. I  
10 just was curious because it's not here in today's  
11 presentation. Yes, I did see it. Again, I know it's  
12 not in the presentation and I just wanted to make sure  
13 it was on the table here.

14 The discussion about the road map was also  
15 not in your letter but it was discussed heavily during  
16 the discussion meeting -- your draft letter. Thanks.

17 MR. NGUYEN: Next slide, please.

18 During the November 17th subcommittee  
19 meeting the staff received several feedbacks from the  
20 members. This slide and the next few slides will show  
21 those feedbacks and the staff-proposed response.

22 For feedback number one, the concern was  
23 the draft guide does not contain guidance addressing  
24 external electronic data communication control and  
25 access. The staff will revise the draft guide to

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1 provide an example indicating the use of hardware-  
2 based uni-directional communication. It's an approach  
3 that the staff considers acceptable.

4 Any questions on this slide?

5 Next slide, please.

6 The second feedback was the use of the  
7 wireless capability for measure and test equipment, or  
8 MTE, will potentially compromise the safety  
9 functionality, such as potential unwanted software is  
10 downloaded wirelessly prior to disabling the wireless  
11 function. Thus, the MTE becomes a pathway for  
12 unwanted software.

13 However, significant guidance in the  
14 document exists to provide for both control and the  
15 use of wireless technology at the nuclear power  
16 plants. These include the design and operational  
17 controls, as noted in the slide.

18 IEEE Standard 7-4.3.2 requires that  
19 portable MTE be maintained, controlled, and accessed  
20 in a secure location with access limited to authorized  
21 persons only. Further, in addition to the all the  
22 restrictions for use of the wireless technology, Reg  
23 Guide 5.71 contains specific operational controls that  
24 require the MTE is checked prior to use in a critical  
25 reach of access.

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1           Therefore, the staff believes these  
2 controls are adequate and sufficient. And the staff  
3 does not intend to incorporate additional guidance  
4 into Reg Guide 1.152.

5           MEMBER BROWN: I have a comment on that.  
6 I looked at C-4.2 and I had a hard time finding this  
7 that states the checking and documenting. I've been  
8 through all the 4.1, 2.1, 2.2, et cetera, et cetera.  
9 And 5.71 is the general document that says this is how  
10 you configure your entire program.

11           The comments I was making in the  
12 subcommittee meeting were referring to how you do this  
13 operationally. We've got M&TE. We've got wireless  
14 stuff hooked up to those things to bring you whatever  
15 they're doing, updates or other stuff that you're  
16 going to use as part of your test and evaluations,  
17 stuff like that.

18           I'm not quite sure how we'll address this  
19 thought process in the letter now. I do have a  
20 discussion of it, but this is a very generalized  
21 overall what you should do, not how do you execute  
22 when you're doing the design.

23           Guide 1.152 is the design. You say that  
24 in your thing. It's one of the primary design  
25 documents and guidance that you have. The idea that

1 in this other programmatic thing sitting over here  
2 somewhere it says you ought to be doing something, the  
3 actual execution, I'm still somewhat wary of that. We  
4 can discuss this more after you finish.

5 MR. NGUYEN: Yes.

6 MEMBER BROWN: We'll probably do that when  
7 I do the letter because I do have a section on this  
8 issue in the letter.

9 MR. NGUYEN: Thank you for the comment.

10 Mike, can you bring up the document, IEEE  
11 Standard 7-4.3.2, on page 29?

12 MR. EUDY: Sure. Hold on a second.

13 MR. NGUYEN: Yes, on the slide.

14 MEMBER BROWN: You said Reg Guide 5.71  
15 contains the following and that's C-4. It's not in  
16 the --

17 MR. NGUYEN: Yes.

18 MEMBER BROWN: Okay. I just wanted to  
19 make sure we were on the same page.

20 MR. NGUYEN: Because you said these are  
21 the programmatic documents. I would like to bring up  
22 7-4.3.2 as endorsed by Reg Guide 1.152 for the exact  
23 guidance. If you look at page 29 and the subclause  
24 5.9.1, the last three paragraphs on that subclause  
25 provide the guidance on how to safely control the MTE.

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1 MEMBER BROWN: All it says is access to  
2 permanent or portable engineering work stations and to  
3 M&TEs shall be limited to a defined set of authorized  
4 employees. You're talking about 5.9.1?

5 MR. NGUYEN: Yes.

6 MEMBER BROWN: That's the last -- I've got  
7 the document open right in front of me.

8 MR. NGUYEN: If you look at the last three  
9 paragraphs, the three short paragraphs --

10 MEMBER BROWN: Yes.

11 MR. NGUYEN: -- these provide the specific  
12 guidance for how to control the MTE equipment.

13 MEMBER BROWN: It's if you think wireless  
14 is okay, it tells you what you should do. If you  
15 don't think wireless should be used, it doesn't. The  
16 issue is should you or should you not be using  
17 wireless communications to update and utilize M&TE and  
18 that type of stuff. This thing says you've got to be  
19 careful if you use wireless.

20 MR. NGUYEN: No. This particular  
21 subclause doesn't provide guidance for wireless. It's  
22 for MTE. If you want to use MTE in the safe zone  
23 inside the fence, you have to follow this guidance  
24 first, regardless of if you have the wireless capable  
25 or not. All the MTE has to follow these provisions.

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1           MEMBER BROWN: Scroll a little higher to  
2 access controls. Lower, I mean, so that access  
3 controls comes up. It closes out the first paragraph.  
4 Now down a little bit. Put those three paragraphs --  
5 now bring in more of 5.9.1. Scroll down -- no, up a  
6 little bit so you get those last -- that's it.

7           It's the last paragraph down there that  
8 talks about disabling and once you go to do the  
9 hookup. There's two aspects here. Nobody's going to  
10 disagree with that.

11           You're obviously not -- well, maybe it's  
12 not obvious, but the point was this effectively says  
13 we allow the use of wireless to update, do whatever it  
14 wants to do to all the M&TE equipment and anything  
15 else we decide we're going to use, portable work  
16 stations or other work stations.

17           And then up above that it says if you're  
18 going to do it then you're going to only have good  
19 people, cleared people. Permanently connected work  
20 stations shall be installed in a plant area that's not  
21 accessible, that provides physical security. That's  
22 not wireless security.

23           And in the first paragraph it says  
24 engineering stations that interface with safety  
25 equipment shall be maintained, controlled, and

1 accessed in a physically secure location. It has  
2 nothing to do with is wireless okay or not. It just  
3 says if you protect it physically, you're happy.

4 And the issue that I have -- this is me.  
5 The rest of the committee may not agree with me when  
6 we go through the letter. The issue I have is  
7 physical protection isn't worth a hangnail in this  
8 circumstance. It's the fact that it's sitting out  
9 there downloading stuff at other times, updates,  
10 whatever they are.

11 You disconnect everything and it's in a  
12 nice, physically secure location. That still doesn't  
13 protect you with wireless unless you put a copper  
14 shield around the entire building so you don't get any  
15 wireless, which you might as well just disconnect the  
16 wireless in the first place.

17 That's the point. Now, whether anybody  
18 agrees with me or not is another issue. I'm just  
19 saying that's something that we will have to settle  
20 amongst ourselves.

21 I understand your point about the physical  
22 security, the access via the IEEE standard. I don't  
23 have any problem with those in terms of what they say.  
24 They are valid. But they don't address the basic  
25 where I'm sitting here all alone in a secure facility.

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1 I can be attacked, downloaded, and have some stuff  
2 residing.

3 And to think you're going to go in --  
4 every time you go to get a maintenance test or every  
5 time you sit down with a portable work station, you're  
6 going to disable that and then run through a complete  
7 virus scan for everything that's on it, that is  
8 operationally probably not real doable.

9 MR. BENNER: This is Eric Benner. Member  
10 Brown, we don't dispute that vulnerability. But for  
11 us, like Khoi started with the main purpose of this  
12 document, our endorsement of this document is a  
13 methodology to meet the requirements in 10 CFR  
14 50.55(h), which incorporates by reference IEEE 603.

15 So that's why not only do we say this  
16 exists from that standpoint, but the concerns you've  
17 talked about we see more as -- I think you alluded to  
18 them -- operational concerns. And the operational  
19 management of M&TE falls more under the program that  
20 licensees do in response. And our staff's guidance is  
21 5.71. Those things are complementary.

22 So it's a matter of those requirements,  
23 the cyber security requirements aren't contained in  
24 50.55(h) or IEEE 603. So that's why --

25 MEMBER BROWN: It was 1991.

1 MR. BENNER: That's right.

2 MEMBER BROWN: But that's --

3 MR. BENNER: I understand. But from our  
4 standpoint, cyber security is regulated as an  
5 operational program in a different part of the  
6 requirements. And this guidance isn't in any way for  
7 demonstrating compliance to those requirements.  
8 There's different guidance for demonstrating  
9 compliance to those requirements.

10 Certainly the committee will deliberate  
11 and come to the conclusion it comes to. But for us,  
12 we're trying on one level to keep some of this  
13 cleaner.

14 We try to reference appropriately where  
15 these -- we do believe that licensing and cyber  
16 security clearly have complementary aspects to them.  
17 So we work heavily with NSIR to try to make sure the  
18 right linkages are there, both from a design and  
19 licensing standpoint and an operational oversight  
20 standpoint. We'll certainly respect where the  
21 committee comes out.

22 MEMBER KIRCHNER: I share Charlie's  
23 concern. Does a piece of test equipment if it's  
24 connected to a safety-related digital system or  
25 digitally based system, does that by default become a

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1 critical digital asset, and therefore before you would  
2 connect such test equipment to a safety-related system  
3 you would have to check it for malware?

4 MR. BENNER: I see that Kim Lawson-Jenkins  
5 has her hand up, and she could speak much more  
6 authoritatively than me on this.

7 MS. LAWSON-JENKINS: Hi. Thank you.

8 My name is Kim Lawson-Jenkins. I work in  
9 the Cyber Security Branch of NSIR. And yes, it is a  
10 requirement.

11 First of all, the M&TE is not a CDA.  
12 However, when it is connected to a CDA or a safety-  
13 related device, it has to be protected at the same  
14 level as the device it's connecting to. So if a  
15 vendor comes in and connects to that device, they have  
16 to assure the licensee that it is protected at that  
17 level when they're connecting it.

18 That is one of the main reasons we don't  
19 have the requirement on what the vendor does when he's  
20 using the M&TE within a secure development  
21 environment. Once you're connected to the device is  
22 when it's really important to know that there is no  
23 malware on that device.

24 There are best practices. They are not in  
25 this document. For instance, you have things like



1 least functionality, which I think is exactly what  
2 you're alluding to when you're saying no wireless  
3 capability should be on the device.

4 But that in itself does not inherently  
5 make the device more secure. I know it may seem like  
6 it that you think there are less attack pathways, but  
7 what's really making it secure is that you have, as  
8 we've said in this document that we're looking at  
9 right now, tightly controlled access to that device.

10 If malware ever gets on the M&TE, it is  
11 there. The salient point then isn't how it got on  
12 there. It's to be able to recognize that you have  
13 malware on a device and then to remove it before  
14 connecting it to a critical digital asset.

15 So I'm not disputing or saying that  
16 wireless is not important at all, but the important  
17 thing that you have to do when you're connecting MT&E  
18 to a device is, first of all, not to do it wirelessly;  
19 to have a wired connection so that when you're doing  
20 the data transfer there's no question that you have a  
21 secure connection.

22 And the next step is to make sure that  
23 before you connect that device, that MT&E, that it is  
24 clean; it does not have malware on it. And if a  
25 vendor has done all the other best practices of having

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1 the least amount of software on there, to have  
2 functions only needed to support the critical digital  
3 asset, that should make it secure.

4 So I just question -- and I understand the  
5 issue about wireless, but removing that access before  
6 you even do a connection doesn't really inherently  
7 make it more secure. That's the point I'm trying to  
8 make. I'm not saying it doesn't, that it absolutely  
9 doesn't make a difference. I'm not saying that.

10 But the amount of benefit that you're  
11 getting, more benefit would be coming from verifying  
12 that you have the least amount of functionality that  
13 you need on there to support that digital critical  
14 asset. And then to be able to do comprehensive scans  
15 of that device to make sure that there's no  
16 unauthorized software on it and there's no known  
17 viruses on that device.

18 I know that was a long answer to the  
19 original question. We're trying to ensure that when  
20 you connect that device, it's protected at the same  
21 level as the CDA that you're connecting to. And the  
22 history of how things got on it may not be relevant.  
23 You just want to make sure at that moment when you're  
24 connecting it that it is secure.

25 MEMBER BROWN: I don't disagree with that,

1 that it's secure when you connect it, but it's not  
2 always just a vendor that comes in and brings his own  
3 stuff in. The plants have their own operational  
4 equipment where they have to do periodic this or  
5 periodic that, and that's M&TE at the same site of the  
6 same kind.

7 MS. LAWSON-JENKINS: Yes.

8 MEMBER BROWN: If it's sitting in a room  
9 physically secure but wireless connected, that means  
10 it's open. Depending on the configuration of it at  
11 the time, a lot of stuff -- when I've got my laptop  
12 just sitting around and it's off, information gets  
13 into it. I find that out when I turn it back on.

14 Once you've got a connection of any kind,  
15 whether it's a hardwired connection or a wireless  
16 connection, it's downloading. So that means every  
17 time you go to use that piece of test equipment, a  
18 plant technician, before he does anything he's got to  
19 go do a complete whatever, virus protection. They've  
20 got to go through the whole rigmarole --

21 MS. LAWSON-JENKINS: Yes, they do.

22 MEMBER BROWN: -- before they actually go  
23 in and do any calibrations, testing, or anything else.  
24 That's what that would mean.

25 MS. LAWSON-JENKINS: Yes.

1 MEMBER BROWN: So I understand that the  
2 plant would have to --

3 MEMBER KIRCHNER: That's what I was  
4 asking, Charlie --

5 MEMBER BROWN: Yes.

6 MEMBER KIRCHNER: -- if that is explicitly  
7 stated somewhere. If not in this reg, does it exist  
8 in --

9 MEMBER BROWN: That's the licensee --

10 MEMBER KIRCHNER: -- in your world -- I'm  
11 trying to think of which of the applicable reg guides  
12 for cyber security, but is that explicitly stated?

13 MS. LAWSON-JENKINS: That is explicitly  
14 stated in the section that was referenced on the  
15 slides that were presented. It's also in the same reg  
16 guide for portable media and mobile devices.

17 That includes M&TE where it says that you  
18 must connect it -- when you connect it, it has to be  
19 protected at the same level. I know I gave Khoi some  
20 information about scanning the devices also.

21 Admittedly, all of these things happen in  
22 the operational state. I absolutely agree with Member  
23 Brown on that. That is where it's occurring. And  
24 even before the device comes to the plant it has to be  
25 checked, and there has to be assurance that it has

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1       been maintained in a secure fashion. So part of the  
2       oversight that is occurring when you're speaking to  
3       the vendor is how do they keep these devices secure.  
4       And at the --

5               MEMBER BROWN: Excuse me. It's not just  
6       vendors. I mean, you don't call vendors in just to do  
7       stuff you have to do routinely, I don't think. We  
8       used to do it ourselves. Our operators did all the  
9       testing and everything else.

10              I'm not a commercial plant operator, but  
11       I'd presume commercial plants have electronic  
12       technicians on their staff that do all their  
13       calibrations and updates. You don't call in  
14       Westinghouse or whoever did it at the time, whoever  
15       designed the stuff to do that for you every time.

16              So bringing stuff into the plant, that's  
17       covered. If you're going to bring something in and  
18       it's going to be from outside the plant, people are  
19       going to say, hold it. You can't use that until --  
20       and they'll go check it. If the wireless is disabled  
21       when they do that, you're probably golden.

22              I'm talking about stuff that's available  
23       to the plant operators and the technicians, and it's  
24       sitting in a secure facility where it's controlled.  
25       It's logged and it knows the calibration period. It's

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1 all set up. So that's all parked in, but it's got a  
2 wireless connection.

3 Most of the new test equipment is all  
4 software controlled. You can't get away from it  
5 except the old analog volt meter. Well, not even  
6 those anymore. They've got microprocessors in them.

7 So it's just a source that now says if you  
8 allow that stuff to be updated -- again, if your  
9 wireless is connected, even if it's off, it's  
10 downloading. That means every time you go test that  
11 stuff, even though it's been validated and checked  
12 before the last time you used it, you've got to go  
13 through the whole drill of reverifying whether it has  
14 been contaminated or some cyber attack has gotten  
15 through to it.

16 MS. LAWSON-JENKINS: And that is true.

17 MEMBER BROWN: Okay. So we're on the same  
18 page from that stance.

19 MS. LAWSON-JENKINS: Yes. Okay.

20 MEMBER BROWN: The one way to get around  
21 that is to not have test equipment ever hooked up to  
22 wireless. If you need to update it, hook it up to a  
23 cable where you know when you do it explicitly. And  
24 then you can download and check that you didn't get  
25 any malware downloaded.

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1           Although remember, all your cyber security  
2           equipment, you're checking for what you already know,  
3           not for what you don't know. It's very reactive.  
4           That's why everybody keeps getting hacked. Somebody  
5           figures out how to do it again. So I'm just  
6           skeptical.

7           Again, this is my view. This is not the  
8           committee's view. This is my view. And I've included  
9           a section in the letter that we'll be able to discuss  
10          it and come to an agreement. This has been, I think,  
11          a helpful discussion to let everybody hear a little  
12          bit more than me talk.

13                 MEMBER BLEY: Charlie?

14                 MEMBER SUNSERI: I think you're right --

15                 MEMBER BROWN: Matt, what did you say?

16                 MEMBER SUNSERI: Let Dennis go.

17                 MEMBER BROWN: Okay. I don't want to  
18          forget you.

19                 Dennis?

20                 MEMBER BLEY: Yes. I'm following that  
21          discussion or trying to. I want to make sure I get  
22          your point on this. It's almost like you're telling  
23          the folks in the plants they don't want to do this and  
24          they've got to make sure it doesn't have that  
25          capability.

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1 I'm curious from the staff's point of  
2 view, even if you don't have wireless access, you have  
3 a physically secure place but people can go in and out  
4 of there who are authorized. The thing I've been  
5 hearing is this is a lot of burden to have to do a  
6 full scan on the test equipment you bring out of that  
7 secure facility.

8 Even if they don't have wireless access,  
9 do you still have to do the same kind of scans and  
10 things?

11 MEMBER BROWN: I would think -- sorry,  
12 Dennis.

13 MEMBER BLEY: I wanted to hear from the  
14 staff on that, Charlie.

15 MEMBER BROWN: Okay. I didn't know who  
16 you were asking.

17 MS. LAWSON-JENKINS: Yes. They will have  
18 to do the same procedure because it isn't a matter of  
19 -- they have to maintain the integrity of the device.  
20 As you just mentioned, you have physical access.

21 Even when you have wired access, if you  
22 have an affected vendor, the website where you're  
23 going to do the download, and if you have a wired  
24 connection that you're connecting to the internet, it  
25 is still possible to download malware that way.

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1                   MEMBER BLEY: Okay. So I'm trying to get  
2 this straight. From the point of view Charlie's been  
3 arguing, if you get rid of one of those vectors to  
4 come in, that means you've cut out one possible route  
5 but there are still others.

6                   From the practical side of I go in and get  
7 a piece of equipment, I've got to do the same checks  
8 on it whether or not there's wireless capability. So  
9 there isn't any real savings in a practical sense  
10 other than we know we've cut out one possible vector  
11 out of many.

12                  MS. LAWSON-JENKINS: And if you're  
13 allowing wireless in the plant, they're doing scans to  
14 see the type of connections that are occurring. So I  
15 believe one of the concerns that Member Brown has  
16 should be captured in the scans, especially in areas  
17 where you have maintenance equipment that you're going  
18 to be connecting to other devices.

19                  MEMBER BLEY: Okay. Thanks.

20                  Charlie, I kind of cut you off. Did I  
21 misstate your concerns?

22                  MEMBER BROWN: You didn't misstate. You  
23 just didn't -- what's the right -- you said if you  
24 don't have wireless. And somebody said you've got to  
25 connect by cable. Well, it goes two ways.

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1           The M&TE is not connected to anything.  
2           It's not connected by cable. It's not connected by  
3           wireless. Physically you can control the cable. You  
4           can't control the wireless as easy if it's on, whereas  
5           with a cable you disconnect it and away you go.

6           You can do the same thing with the  
7           wireless. That's the best way to do it, to not have  
8           it at all. And then when somebody comes in to get the  
9           equipment, it has been certified the last time. If  
10          it's physically secure and nobody's come in, that  
11          doesn't prevent the same thing we always worry about.

12          Even a vendor can come in to upgrade  
13          software on a piece of safety equipment, which  
14          everybody says is okay but somehow down there it's  
15          buried. They introduce it and away you go. That's a  
16          physical check that you have to do every time. It's  
17          just one more way for equipment to be compromised.

18          Matt, you were going to say something.

19          MEMBER SUNSERI: I was just --

20          CHAIRMAN REMPE: Jose's had his hand up  
21          too, just to keep track.

22          MEMBER BROWN: Okay. I didn't see that.

23          MEMBER SUNSERI: This is Matt. I was just  
24          going to confirm -- at least my time in the plants is  
25          getting pretty dated now -- the plants are very

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1 attuned to that and calibrating what they're going to  
2 connect into the plant. So they do the scans all the  
3 time.

4 MEMBER BROWN: Okay.

5 MEMBER SUNSERI: They check it out. As I  
6 recall, there was even two people involved so that you  
7 weren't relying on a single person that could be  
8 coding something in there without somebody watching  
9 them.

10 MEMBER BROWN: Jose?

11 MEMBER MARCH-LEUBA: Yes. Thank you.

12 MEMBER BROWN: Are you done, Matt?

13 MEMBER SUNSERI: (No audible response.)

14 MEMBER BROWN: Jose, go ahead.

15 MEMBER MARCH-LEUBA: Yes. I just wanted  
16 to warn against the false sense of security that I  
17 keep hearing from the staff. We have a requirement  
18 that the thing be clean and you will clean it. Yes.  
19 Everybody in the world will scan their Windows  
20 computer and Google Chrome for vulnerabilities, and it  
21 was coming out green and clean.

22 Just this week Google issued an emergency  
23 patch for a vulnerability that was being exploited.  
24 So just because we were running Windows Defender or  
25 sophisticated McAfee on the system and we were not

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1 finding a vulnerability, it doesn't mean it wasn't  
2 there. Everybody that has a Windows computer or  
3 anybody that uses Google Chrome had a vulnerability  
4 that was scanned negative last week and it was a false  
5 negative. So just the fact that you scan doesn't mean  
6 it's not there.

7 Let me give an example from other areas of  
8 our field. We our design our pipes to be seismically  
9 qualified. We scan them regularly for cracks. But  
10 nevertheless, we assume the pipes will break and you  
11 will have LOCAs. Even though you design it to be  
12 perfect and you scan it to be perfect, you still say,  
13 what happens if it breaks.

14 In the area of cyber security, we have to  
15 keep everything very controlled. We have to scan for  
16 vulnerabilities. But you have to do the extra step of  
17 assuming that LOCA is going to happen. What will you  
18 do then? How will you prevent it?

19 I keep hearing this extremely false sense  
20 of security from the staff. We had it 12 years ago.  
21 They told us they were going to keep it clean. They  
22 don't. They cannot do it. Okay, just getting it on  
23 the record.

24 MEMBER BROWN: Any other comments?

25 MS. LAWSON-JENKINS: This is Kim Lawson-

1 Jenkins. I would like to briefly reply to that. I  
2 honestly don't believe anyone in the cyber security  
3 community has a false sense of assurance about  
4 attacks.

5 The hackers are very sophisticated. They  
6 are always changing their methods. They are always  
7 trying to exploit vulnerabilities. They are always  
8 trying to misuse protocols or functions that will  
9 become vulnerabilities that they can exploit.

10 So I'm sorry if I gave the impression that  
11 scanning is the end-all to be all. It is only one  
12 tool in the tool box, which must be used correctly to  
13 be able to identify, as you said, known  
14 vulnerabilities. I mentioned having a reduced amount  
15 of software and only necessary things on the device  
16 will help with those unknown vulnerabilities, things  
17 that people can exploit in the future.

18 MEMBER MARCH-LEUBA: Yes. I want to make  
19 a point to apologize to you because I know you are  
20 very good and you take it seriously.

21 Just think of what other people do,  
22 especially the ones that come from the management  
23 side. We had a member just mention how seriously they  
24 take the scans. When you don't know as much as you  
25 and I know, you think that the scan saves you. A scan

1 is just one thing you should and must do, but it  
2 doesn't protect you 100 percent.

3 When we leave the money man in charge of  
4 the implementation, there is a big tendency to save  
5 money. You have to because otherwise your plant won't  
6 run and you have to close it.

7 MS. LAWSON-JENKINS: I'm afraid I've  
8 hijacked Khoi's meeting. I didn't want this to become  
9 a cyber security discussion. I honestly look forward  
10 to continuing these discussions, but I want Khoi to be  
11 able to finish his presentation.

12 MEMBER BROWN: You're doing just fine,  
13 Kim. Don't worry about it.

14 MEMBER MARCH-LEUBA: Yes. I see my job in  
15 life to scare everybody, put a little bit of the scare  
16 I have in my blood into yours. Thank you.

17 MR. BENNER: This has been a good time.  
18 This is Eric Benner again. I turned it over to Kim.  
19 I'm glad Kim led the discussion because she has a lot  
20 more of the detail as to how cyber security works.

21 I'm going to bring it back to a different  
22 level in that the words that are in the standard are  
23 the words in the standard. We influence standards.  
24 The NRC has membership on the standards. We influence  
25 the standards but we don't dictate what's in the

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1 standards.

2 And for our purposes, when we look at a  
3 standard we're looking at: is there anything here  
4 objectionable? We certainly don't find anything  
5 objectionable in that last statement. We understand  
6 about wireless capability shall be disabled prior to  
7 connecting. We certainly don't find anything  
8 objectionable to that part of the standard.

9 We don't use -- as I alluded to, this is  
10 for the staff's review. This guidance was reviewed as  
11 a way for licensees to meet IEEE 603, which is in the  
12 safety-related portions of the standard, 10 CFR Part  
13 50. None of that is about cyber security.

14 So where we're at is there is other  
15 guidance for how you address cyber security, including  
16 control of wireless, access, and connections. What  
17 I'm going to keep repeating is no matter what we put  
18 in this guidance document, it has no bearing on what  
19 a licensee does operational to demonstrate compliance  
20 with the security requirements in 10 CFR Part 73.  
21 That's why we're drawing a distinction here.

22 MEMBER BROWN: Before you go on, I will  
23 continue this for just a moment since I'm kind of  
24 leading this from my standpoint. I'll either have the  
25 final word or somebody else will want to say something

1 else.

2 The perspective I come to, I'm dividing it  
3 between work stations and M&TE. We've been talking  
4 about M&TE. To me, M&TE equipment sits in a room  
5 where it's logged. It has a set of paperwork that  
6 goes along with it or software work on some other  
7 computer that says it was last calibrated at a certain  
8 time and therefore it's okay to be used through this  
9 period.

10 And if that equipment is sitting on a  
11 shelf and it's not connected either wirelessly or by  
12 cable, the likelihood of something interfering or  
13 coming into that piece of equipment is pretty darn  
14 low. There's no doors.

15 You put away the wireless, but now let's  
16 say you've got it connected to an internet connection.  
17 Well, that's a problem. I would disagree with that  
18 also.

19 If you need to upgrade the software  
20 because the vendor who makes that test equipment says  
21 we're not measuring that stuff right and we have an  
22 error in our software, he'll come in. You don't want  
23 him to send any of it down to you.

24 You want his little body to go trucking  
25 through the plant with all the other security to make



1       sure it's the right guy, with the right credentials,  
2       with the right whatever to change and update all the  
3       same pieces of equipment to the new software where  
4       they can then do the scans and it's done. It doesn't  
5       mean he didn't bring something in, but you  
6       theoretically would check to make sure he didn't bring  
7       something in with some capability that the site had  
8       put together.

9               So my viewpoint that I come from, at least  
10       in the programs I operated and developed for 22 years  
11       once we had computer stuff, is just because  
12       something's nice and easier to do, you ought not do it  
13       if it has the potential to cause problems. With M&TE  
14       it's easy to not do it.

15              Work stations are a character. You're  
16       doing stuff. They're communicating with things.  
17       They're bi-directional. They're getting information  
18       in.

19              By hooking them up wirelessly and you say  
20       all wireless should be disabled, to me, I don't know  
21       if that means when somebody's following this guidance  
22       that the work stations that you've got in various  
23       locations would have no wireless connection. They may  
24       have an internet connection because of their bi-  
25       directional operation in and of itself, but they don't

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1 have another pathway where something can come in.

2 Do I read that first sentence correctly?

3 It says shall be disabled on work stations. Kim,

4 would you expect a licensee to follow that rigorously?

5 Are you still there?

6 MS. LAWSON-JENKINS: I'm still here. All

7 capabilities disabled, all wireless work stations --

8 MEMBER BROWN: Yes. All wireless

9 capabilities shall be disabled on work stations.

10 There are two sentences in that last paragraph.

11 MS. LAWSON-JENKINS: Yes, I see both of

12 them.

13 MEMBER BROWN: I'm not talking about M&TE

14 now. Put that one aside.

15 MS. LAWSON-JENKINS: Okay. If that's the

16 requirement. That's why they say disabled too. My

17 preference would be not even to have the capability.

18 MEMBER BROWN: Absolutely. I love you.

19 MS. LAWSON-JENKINS: Yes. It could even

20 be that if you're going to do something, I would

21 prefer not to have the capability rather than

22 disabled. But they may not be able to --

23 MEMBER BROWN: No work station should have

24 wireless enabled, attached, or involved.

25 MS. LAWSON-JENKINS: That's a very

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1 customized work station where you don't even have that  
2 capability, which is why this standard is probably  
3 written this way.

4 MEMBER BROWN: All right.

5 MEMBER BLEY: Charlie?

6 MEMBER BROWN: Yes, Dennis.

7 MEMBER BLEY: We've gotten into an area  
8 where the words matter and how the words are  
9 interpreted matter, and that's not in what we're  
10 reading.

11 Even quite a few years ago there were  
12 places to go with your computer where you weren't  
13 allowed to have a camera on board the computer. And  
14 it hit a point I forget how many years ago where you  
15 can't even buy one. You'd have to design it yourself.

16 But when you ran into language like that,  
17 it didn't mean to turn a switch and turn it off. It  
18 meant you had to have somebody go in and remove the  
19 actual camera from the device.

20 I guess it's not clear to me what this  
21 precise word means by disabled. Does that mean it's  
22 removed, it's destroyed, so it's not just turning a  
23 switch and turning it off?

24 MEMBER BROWN: It's not clear. You're  
25 right. I interrupted you. I'm sorry. I thought you

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1       were done.

2                   MEMBER BLEY:   It's the staff's words so  
3       I'm wondering what it means to them.

4                   MEMBER BROWN:   This is the IEEE standard  
5       now, the 7-4.3.2.

6                   MEMBER BLEY:   Well, yes but through the  
7       reg guide they're endorsing it.

8                   MEMBER BROWN:   Absolutely.

9                   It's muted.   I hear nothing.

10                  MR. NGUYEN:   So this is a long discussion.  
11       The staff appreciates all the comments and questions,  
12       but I would like to summarize the staff decision on  
13       this subject.

14                  MEMBER BLEY:   I guess there's no answer to  
15       that question.

16                  MEMBER BROWN:   We'll have to discuss it  
17       more on our letter when we get there, how we want to  
18       deal with this discussion.

19                  MR. NGUYEN:   So the staff believes that --

20                  MEMBER BROWN:   Were you going to say  
21       something else, Matt?   You looked like you --

22                  MEMBER SUNSERI:   No.   I mean, I'm going  
23       back on my memory again but when we were working with  
24       the interfaces, if it said disabled, it was disabled.  
25       You couldn't use it anymore.   It was physically

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1 plugged or disconnected or something. It wasn't  
2 turned off.

3 MEMBER BLEY: That's what I would have  
4 expected. That's what I had to do with the camera in  
5 my old computer.

6 MEMBER SUNSERI: I remember the early days  
7 of laptops. Disabled meant in terms of portable media  
8 that epoxy was put into the plug-in ports on the  
9 computer to prevent people from doing bad things.

10 MEMBER BROWN: Disabled is a stronger word  
11 than turned off. I read that strongly, but you bring  
12 a good point. I didn't think of your thought process,  
13 Dennis.

14 MEMBER BLEY: That's what it meant to me,  
15 but I thought it would be very clear to the staff. It  
16 wasn't supposed to be a hard question.

17 MEMBER BROWN: Any other comments on this  
18 subject?

19 We'll let Khoi continue. Thank you very  
20 much for allowing us to diverge.

21 MR. NGUYEN: Before I continue to the next  
22 subject, I would like to summarize this. I mean, it's  
23 a lengthy discussion but the staff's decision on this  
24 subject is it's very important that a requirement is  
25 in place to make sure there's no malware in the M&TE

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1 devices before connecting to the safety equipment.

2 And we feel both the IEEE standard and the  
3 Reg Guide 5.71 -- we found there's significant  
4 guidance and measures in place that ensure there's no  
5 malware existing in the M&TE before connecting to the  
6 CDA.

7 So regardless of whatever method that the  
8 malware gets into the M&TE, I think there's a measure  
9 in place that's protecting, scanning, or whatever to  
10 identify any malware and remove it before connecting  
11 to the CDA. I think that is a sufficient safety  
12 measure, for the M&TE to be connected through the CDA.

13 MEMBER KIRCHNER: Khoi, could you go back  
14 to your view graphs? I just wanted to look at the  
15 view graph again.

16 MEMBER BROWN: Back to the presentation?

17 MEMBER KIRCHNER: The presentation, sorry.

18 MR. NGUYEN: Mike, could you bring back  
19 the slide?

20 MR. EUDY: Will do. Give me a second.

21 MEMBER BROWN: I think it was slide 8.

22 MR. EUDY: It's up. Does everyone see it?

23 MR. BENNER: Yes. Thank you, Mike.

24 MR. NGUYEN: Do you have a question on  
25 this slide?

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1 MEMBER KIRCHNER: Okay. Thank you.

2 MEMBER BROWN: That's where we were. So  
3 you can proceed now.

4 MR. NGUYEN: Slide 9, please, Mike.

5 For the third feedback, the concern was  
6 Clause 5.17 of the 7-4.2.3, the self-reference to  
7 Annex C, Dedication of Existing Commercial Computers.  
8 This reference in a way contradicts the exception of  
9 endorsement of the Annex C. In other words, we are  
10 not endorsing Annex C. We are endorsing Clause 5.17,  
11 but the clause is a reference to Annex C. So there's  
12 a contradiction.

13 The staff will revise the draft guide to  
14 clarify that Clause 5.17 provides criteria that the  
15 NRC staff finds acceptable for the use of commercial  
16 equipment in safety-related systems in nuclear power  
17 plants.

18 Clause 5.17 references Annex C for  
19 additional information on commercial-grade items  
20 except for the dedication. However, while there is a  
21 useful history record and referenced information in  
22 Annex C, the NRC staff does not see the need to  
23 endorse such information. So the staff will make a  
24 clarification --

25 MEMBER BROWN: I totally lost the bubble.

1 MR. NGUYEN: Okay. This draft guide  
2 endorses Clause 5.17 of IEEE Standard 7-4.3.2. But  
3 the staff has not endorsed Annex C of the standard.

4 MEMBER BROWN: Got it.

5 MR. NGUYEN: However, Clause 5.17  
6 references Annex C.

7 MEMBER BROWN: So by default you endorse  
8 it?

9 MR. NGUYEN: We make the statement in the  
10 standard that --

11 MEMBER BROWN: I know you said that, but  
12 I said by default. That was our discussion that we  
13 had in the last subcommittee meeting.

14 MR. NGUYEN: Right. So the staff will  
15 make the clarification in the draft guide to make it  
16 clear that we endorse Clause 5.17 --

17 MEMBER BROWN: But you are endorsing the  
18 alternate methodology as opposed to 1.164 and 1.250,  
19 which had a rigorous review. This has not.

20 I'm paraphrasing our discussion from the  
21 subcommittee meeting. This just popped in. We spent  
22 a large amount of time. NEI documents, topical  
23 reports, two different -- TR is this, TR is that;  
24 1.164 and 1.250 are examples of what they meant.

25 And here there's kind of a broad brush.



1 A page and half says it's okay, just do -- I'm  
2 paraphrasing. I'm not saying do whatever you want.

3 But the method here, which is not as  
4 rigorous at all compared to what we just went through  
5 and wrote a letter on in great detail and yet by  
6 definition you're endorsing that -- I guess in my  
7 personal opinion, I wouldn't endorse 5.17. That's my  
8 personal opinion.

9 MR. NGUYEN: May I have --

10 MEMBER BROWN: Of course you can.

11 MR. NGUYEN: We admit that we didn't have  
12 the clear answer at the subcommittee meeting. But  
13 after the meeting we went back and we looked at 1.250.  
14 We note that the draft guide provides guidance for the  
15 dedication process when affecting the dependability.

16 MEMBER BROWN: That's still dependability.

17 MR. NGUYEN: If the applicant or licensee  
18 chooses to use a third party, then they can use that  
19 draft guide as a supplemental guidance for commercial-  
20 grade dedication.

21 Clause 5.17 provides the traditional  
22 commercial-grade dedication process. We have been  
23 using and reviewing the commercial-grade dedication.  
24 So there's no conflict with the two.

25 We didn't answer clearly at the

1 subcommittee meeting that there's different methods.  
2 One draft guide is for the specific guidance and this  
3 reg guide for the traditional method.

4 MEMBER BROWN: The 1.250 was admittedly  
5 still level with dependability, but it also was highly  
6 dependent upon the previous 1.164, the NEI documents  
7 and topical report, a couple of those as a matter of  
8 fact.

9 And this did not seem to be as thorough as  
10 the other approach. It was tough to dig out why this  
11 is now okay as well as the other method, which  
12 involved NEI documentations and examples of how they  
13 would go about executing it.

14 MR. BENNER: It doesn't replace those. I  
15 mean, our thoughts in the first bullet here gets to  
16 that point. Clause 5.17 isn't in conflict with the  
17 guidance.

18 Khoi was focused on 1.250, which is on  
19 using self-certification for dependability. Reg Guide  
20 1.164 is the overall staff guidance for commercial-  
21 grade dedication programs. And this doesn't change  
22 that.

23 MEMBER BROWN: But if it is, why has  
24 something else --

25 MR. BENNER: Because it's not in conflict.

1 Our judgement here is do we find it objectionable, and  
2 we don't. We don't find Clause 5.17 objectionable  
3 because it's consistent with the regulations and the  
4 guidance we have out there. It's not as detailed.

5 But I think if your concern is someone is  
6 going to say, for my commercial-grade dedication  
7 program I just followed 5.17 and I didn't follow Reg  
8 Guide 1.164, the staff wouldn't find that. When they  
9 went out to inspect the licensee's commercial-grade  
10 dedication program, they wouldn't find that  
11 acceptable.

12 And even when we talk about Clause 5.17 in  
13 the reg guide, it references Reg Guide 1.164 as the  
14 staff's overall guidance for commercial-grade  
15 dedication.

16 MEMBER BROWN: Yes. So you accept this as  
17 a standard but that doesn't --

18 MR. BENNER: Right.

19 MEMBER BROWN: -- that doesn't say you  
20 can't use 5.17 and 1.164. You can do it aside from  
21 1.164. You can -- I don't want to say discard it.  
22 You can set that aside. You can use this procedure.  
23 And you're saying you're satisfied with that, the  
24 staff is?

25 MR. BENNER: I'm saying they can't satisfy

1 1.164 just because -- it goes back to the purpose of  
2 this guidance document is for a licensee to  
3 demonstrate compliance with the regulations in 10 CFR  
4 50.55a. Commercial-grade dedication is under 10 CFR  
5 Part 21.

6 If you look at the purpose of this reg  
7 guide, it says nothing about 10 CFR Part 21. If you  
8 want to comply with 10 CFR Part 21, you still have to  
9 follow all the staff guidance available or provide an  
10 alternative to where we've articulated what licensees  
11 need to do to meet 10 CFR Part 21.

12 MEMBER BROWN: Okay. I'm going to go back  
13 and read this one also just for fun.

14 MR. BENNER: It's good, light reading.

15 MEMBER BROWN: So design analysis is part  
16 of the overall thing. You can do it for 1.164.

17 MR. BENNER: Um-hum.

18 MEMBER BROWN: And 5.17.4 literally says  
19 performing one method for documenting this as opposed  
20 to what we say is in Topical Report 106439, which is  
21 the NEI topical report that was referenced via 1.164.

22 MR. BENNER: Um-hum.

23 MEMBER BROWN: That means you can set that  
24 aside and use what was before for performing the  
25 analysis. And I did not go back to the 1.164 and the

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1 topical report, unless somebody wants to pay me for  
2 another two weeks' worth of time over and above my  
3 allotment.

4 So right now it seems to me that, in a  
5 way, we've got some dueling approaches. They are not  
6 both the same. You're saying it looks okay, but it's  
7 not the same as the other one per se.

8 MR. BENNER: It's not in conflict and it's  
9 not guidance for complying with 10 CFR Part 21, which  
10 is where you would address commercial-grade  
11 dedication. We would only take issue with this if  
12 there were something there that was in conflict with  
13 our regulatory requirements. And we just don't see  
14 that.

15 MEMBER BROWN: You don't see that in 5.17?

16 MR. BENNER: No.

17 MEMBER BROWN: Okay. Any other comments?

18 MR. BENNER: One, it's not in conflict.  
19 And two, it is not a guidance for demonstrating  
20 compliance with the regulation in question.

21 MEMBER BROWN: Okay. Using Dennis'  
22 approach of words have meaning, you're saying if they  
23 went through 5.17, that would not be enough to  
24 demonstrate compliance unless they did something for  
25 some other documents as well; 10 CFR, whatever it was.

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1 MR. BENNER: Um-hum.

2 MEMBER BROWN: Because this is not in  
3 whatever part it is, fundamentally they can't use 5.17  
4 exclusively. They have to use it in conjunction  
5 with --

6 MR. BENNER: Well, they can't use this reg  
7 guide. This reg guide isn't for purposes of  
8 demonstrating compliance with that regulation period.

9 MEMBER BROWN: It said it's okay for  
10 approving commercial dedication of EDD. That's what  
11 this is all about, right?

12 MEMBER SUNSERI: Charlie, I think it goes  
13 like this. The commercial-grade dedication has a  
14 part, right. For digital there's some greyness in one  
15 of the areas. And this satisfies that part, but  
16 you've still got to do the other three.

17 MEMBER BROWN: Well, the way the words  
18 read in that one section for the analysis is the other  
19 part is one method, but not necessarily, because  
20 there's a bunch of things they say before getting into  
21 that which define what design analysis is plus some  
22 other stuff. It's okay. I got your point.

23 Any other comments from anybody on this  
24 slide?

25 Okay. Khoi?

1 MR. NGUYEN: Next slide, please, slide 10.

2 The last feedback would be --

3 MEMBER BLEY: Can I sneak in something?

4 MR. NGUYEN: Yes.

5 MEMBER BLEY: I've been stewing over that  
6 conversation a little bit.

7 MEMBER BROWN: The previous slide?

8 MEMBER BLEY: Well, I don't need the  
9 slide.

10 MEMBER BROWN: Okay.

11 MEMBER BLEY: It's the concept of the NRC  
12 staff approach to looking at a standard. I had always  
13 assumed, I guess, that you go to a standard when there  
14 exists a standard to cover something you want to  
15 include in your guidance. You don't just go out and  
16 endorse standards by themselves if they don't have a  
17 real need for the areas you want to provide guidance.

18 This idea that it doesn't conflict with  
19 our other guidance seems -- it just feels odd to me.  
20 It feels like if you don't need it for what you're  
21 doing now, why would it be endorsed? You'd leave out  
22 some parts of standards or their attachments because  
23 they aren't necessary.

24 And this is kind of taking the other view.  
25 Well, we keep it all in unless it conflicts with

1 something on our side. I'm just stating an unease  
2 about the way that process goes. And maybe that's the  
3 way it always goes but it doesn't feel that way to me.

4 I don't know what to do with it, Charlie.  
5 I just wanted to get it out there.

6 MEMBER BROWN: Your point being why  
7 endorse it if it doesn't satisfy -- if you've got a  
8 process in place and it doesn't satisfy anything new?

9 MEMBER BLEY: If it doesn't satisfy any of  
10 the purposes of this particular reg guide.

11 MEMBER BROWN: Okay. Thank you, Dennis.

12 Any other comments before we move on  
13 again?

14 All right. Are we on the next slide,  
15 Khoi?

16 MR. NGUYEN: All right. We are on slide  
17 number 10.

18 So for feedback number four, the concern  
19 was the draft guide does not contain any discussion of  
20 the I&C safety system architecture, including the  
21 fundamental design principles.

22 It should be noted that the scope of Reg  
23 Guide 1.152 is to endorse IEEE Standard 7-4.3.2 as an  
24 acceptable approach to meet the regulation  
25 requirements, which is IEEE Standard 603.

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1           The I&C safety system architecture is  
2           evaluated by the staff in the context of meeting the  
3           four fundamental design principles. It doesn't say  
4           independent and deterministic diversity and defense-  
5           in-depth, or D3. The staff performs its evaluation  
6           using the licensing process guidance in Interim Staff  
7           Guidance or ISG-06 and the Design Review Guide or DRG.

8           Staff believes that while the fundamental  
9           design principles are considered by the staff when  
10          evaluating the I&C safety system architecture,  
11          deterministic D3 are not part of the IEEE 603  
12          requirements. And therefore, they are out of the  
13          scope of this reg guide.

14          Therefore the staff does not intend to  
15          include these design principles in this draft guide  
16          because the staff thinks that this discussion of these  
17          principles in ISG-06 and the DRG is the most  
18          appropriate location for that discussion, not in this  
19          draft guide.

20                 MEMBER BROWN: I would counter that with  
21                 the point that you made in here. I understand ISG-06,  
22                 as I've wrote reports on it and also on all the DRGs.

23                 I don't disagree with your point relative  
24                 to big, big, big picture thought processes. You state  
25                 yourself that Reg Guide 1.152 is one of the primary

1 documents for the use of computers and I&C systems.

2 And the purpose of including this up in  
3 the introduction would be to -- not down in the text  
4 but in the introduction -- put the application of  
5 software-based, computer-based systems, or PDDs in the  
6 new, more expansive view of the world, is to convey  
7 the application of those approaches within an overall  
8 system design, which the architecture is the key  
9 feature of those.

10 So it doesn't dictate anything. It just  
11 says the fundamental without any words. It gives you  
12 new stuff, but it brings a lot of baggage along with  
13 it that you've got to consider when you're doing the  
14 application.

15 It doesn't dictate anything, but it does  
16 state that you've got to be careful because the  
17 primary protection against CCS is a robust, redundant  
18 architecture which has these characteristics. So I  
19 would disagree that that's, from a principle  
20 standpoint, not an unreasonable thing to put in as a  
21 lead into the reg guide.

22 It doesn't dictate doing A, B, or C. It  
23 just says, hey, in the context of applying these  
24 things, they're applied in the overall thing. So it's  
25 a primary document, like you say, the ISG-06, the DRG,

1 but also BTP 7-19 and Reg Guide 5.71 eventually.

2 So 1.152 is one of the linchpin documents.  
3 The concept of how it's applied in an overall  
4 architecture and what is the intent of applying it,  
5 that to me is a philosophical thing that should be  
6 part of it, just as we've included this thought  
7 process into ISG-06 and BTP 7-19.

8 Even though BTP 7-19 is fundamentally  
9 defense-in-depth and diversity, it covers the overall  
10 point of we've got this giant stuff we're providing.  
11 Here's the overarching principles and architecture.

12 If the architecture is the key to safe  
13 operation of all these critical safety systems,  
14 protection systems and the safeguards in particular,  
15 all those that require redundant systems. And that  
16 concept ought to be that this document is part of  
17 that, but here's the overarching thought process. And  
18 that's the purpose of the discussion point that we  
19 talked about in the subcommittee meeting.

20 So I'll just leave it right there. We can  
21 go ahead to the next slide.

22 MEMBER KIRCHNER: We can leave it there.  
23 I would emphasize that we are redundant, Charlie.

24 MEMBER BROWN: That's good, isn't it?

25 MEMBER KIRCHNER: Yes, that's good in this

1 case.

2 MEMBER BROWN: You should not be using BTP  
3 7-19 absent this thought process. You shouldn't be  
4 doing 5.71 without knowing what the system  
5 architecture should be -- what should be embodied.

6 You shouldn't be doing 1.152 without  
7 knowing what that is, and you shouldn't be doing ISG-  
8 06 or the review guides without that centralized  
9 overall architecture thought process in terms of the  
10 safety-related protection systems. That was the  
11 point.

12 Yes, it is redundant. We've put it in  
13 every place. For new people coming in, they start  
14 working on something. Oh, I didn't know that. I'm  
15 over here working, beavering away on diversity.  
16 You're doing that in the context of --

17 MEMBER KIRCHNER: Charlie, I thought you  
18 were going to bring up control of access.

19 MEMBER BROWN: It's in my letter. The  
20 reason control of access is not in this list is I  
21 didn't figure that out eight years and ten years ago  
22 when we did the first Design Review Guide and we did  
23 one of the earlier design certifications. I learned  
24 later.

25 CHAIRMAN REMPE: So I just wanted to do a

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1 time check. I would have thought more slides would  
2 easily be accomplished in the last 20 minutes, but we  
3 do have public comment periods so I just wanted to  
4 make sure that everybody is aware of the time here.

5 MEMBER BROWN: Yes. I'm done with that.  
6 I just wanted to put the context of what this one was.  
7 It doesn't need any more elaboration.

8 MR. BENNER: This is Eric Benner. I'll  
9 take the first step in responding and we'll see if I  
10 get any lifelines.

11 MEMBER BROWN: Is this the same slide or  
12 are you going on?

13 MR. BENNER: No, the same. I'm responding  
14 to --

15 MEMBER BROWN: You want to argue with me?

16 MR. BENNER: No, no, no. I don't want to  
17 argue at all. I think from the standpoint of the  
18 philosophy, the staff is on board with the philosophy.  
19 And the staff has incorporated that philosophy into  
20 the staff review guidance.

21 The challenge we have is the purpose for  
22 regulatory guides is, in this case, endorsing guidance  
23 that can be used to meet the regulatory requirements.  
24 And the philosophy is not embedded in the regulatory  
25 requirements.

1           We do get some pushback when we try to put  
2 philosophy in guidance to licensees. The caution we  
3 get is, you should have a really good line of sight  
4 between anything you're putting in the guidance and  
5 the regulatory requirements. That's why we continue  
6 to point to the staff guidance.

7           We can get into more of those discussions  
8 because it tells how the staff is going to do its  
9 business. And in all honesty, it can get into  
10 philosophy. That's really all I wanted to say in  
11 addition to what we have on the slide.

12           MEMBER BROWN: Well, I will amplify that  
13 because 603-1991 actually embodies at least three,  
14 maybe even four of these. It's independence,  
15 redundancy, and deterministic. It doesn't say  
16 deterministic. I think it's called repeatable or time  
17 response.

18           So three of them are embodied in IEEE 603-  
19 1991, which existed before computer stuff ever really  
20 became involved in these equipments. And the internet  
21 was a bare fledgling of its present capability.

22           If you ever had to operate with -- what  
23 was the first thing? It wasn't email. It was so old  
24 that even I can't remember it now. The first email  
25 stuff, the way you got stuff was sending AOL. Back in

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1 the old, old, old --

2 MR. BENNER: Over your phone?

3 MEMBER BROWN: Yes, over the phone  
4 connection.

5 MR. BENNER: We forgot what that was like.

6 MEMBER BROWN: For a minute.

7 MR. BENNER: And those attributes that are  
8 explicitly in 603, that carries through.

9 MEMBER BROWN: That's what these emphasize  
10 in the reg guide.

11 MR. BENNER: And this goes beyond what's  
12 in 603. That's sort of our challenge.

13 MEMBER BROWN: We'll have to disagree on  
14 that -- with me on that.

15 MR. BENNER: Um-hum.

16 MEMBER BROWN: Next slide. Joy wants to  
17 get that slide 11.

18 CHAIRMAN REMPE: Just want to keep us on  
19 schedule.

20 MR. NGUYEN: Okay, slide 11. Reg Guide  
21 1.152 is one of the primary reg guides used by the  
22 applicants and licensees in development of the I&C  
23 applications, the reactor applications. And these are  
24 the I&C topical reports.

25 MEMBER BROWN: A whole panoply. It's a

1 linchpin, primary reg guide. I love that. You just  
2 argued -- no, you just articulated -- excuse me --  
3 what I've said before.

4 MR. NGUYEN: Yes.

5 MEMBER BROWN: Go ahead. I couldn't  
6 resist.

7 MR. NGUYEN: Okay.

8 MEMBER BROWN: We've got fifteen minutes  
9 left.

10 MR. NGUYEN: So the update to Reg Guide  
11 1.152 is a high priority based on the recent licensing  
12 experience and direction with the stakeholders that  
13 contributed to the update to 7-4.3.2 in 2016.

14 Next slide, please.

15 The staff reports the revision of Reg  
16 Guide 1.152 to update information and guidance in the  
17 areas of functional reliability, design quality, and  
18 the SDOE for programmable digital devices in the  
19 safety-related systems of nuclear power plants to  
20 support NRC guidance and practices to ensure that the  
21 guidance in these areas is current and consistent with  
22 the staff position. Therefore, revision will enhance  
23 the efficiency and the effectiveness of the licensing  
24 review.

25 That will conclude my presentation.



1                   MEMBER BROWN:    I'm not going to be  
2                   contrary here.    I wouldn't disagree with that.    I  
3                   actually thought the revision was pretty well put  
4                   together.

5                   So I didn't have any real problem with the  
6                   approach.        I thought you did a good job of  
7                   incorporating stuff that was in other places.    I  
8                   understand the separation of church and state that you  
9                   want to accomplish in some circumstances.

10                  And I did check between the old 7-4.3.2  
11                  and the new one, paragraph by paragraph, to see what  
12                  was there.    That was painful.    And a comparison of the  
13                  old Rev 3 of the reg guide to this one.

14                  It seemed to connect the dots with the  
15                  exception of these obvious discussion points that  
16                  we've been through.    So I don't disagree that it's  
17                  good to update it the way you did.

18                  Are there any other member comments right  
19                  now?    Anybody on the outside, members?

20                  MEMBER KIRCHNER:   Charlie, I had one.

21                  MEMBER BROWN:    Go ahead.    I didn't hear  
22                  you.

23                  MEMBER KIRCHNER:   I think Dennis raised it  
24                  during the subcommittee meeting and I think I did as  
25                  well.    I really would like to see some kind of flow

1 chart that pulls all of your digital I&C guidance  
2 together. I think it would be very valuable for you,  
3 the staff, to have it in your interactions with the  
4 commissioners as well so you can show the progress  
5 that you've made in this area.

6 And I think it would be very useful for  
7 applicants to sort through how you've connected the  
8 dots, and leave that behind for your successors as  
9 well to show how you can demonstrate that by using  
10 these reg guides and other staff guidance, meeting the  
11 regulations that we were bantering back and forth  
12 today.

13 MR. NGUYEN: Thank you. Thank you for the  
14 comment. You made a good comment.

15 MR. BENNER: Yes. And maybe we  
16 disconnected -- we thought that was outside of the  
17 discussion of this. I recalled it was --

18 MEMBER BROWN: I figured it was in the reg  
19 guide.

20 MR. BENNER: -- we were talking about an  
21 informational brief that we could give to the  
22 committee as to how it all fits together.

23 MEMBER BROWN: That's in the transcript.  
24 That point was made. I went back to that and looked  
25 at that to make sure.

1 I did include yours and Dennis' -- there's  
2 an additional discussion that I put in. We can see if  
3 we want to do it, whatever we want to do, however we  
4 want to rephrase it. I just wanted to make sure I  
5 captured a little bit of the thought process.

6 We need to go to --

7 CHAIRMAN REMPE: Well, before you do that,  
8 when I was looking at the transcript everyone agreed  
9 it should be done. But when does the staff envision  
10 this will be prepared, available, and what document?  
11 Could you give us some details about how you intend to  
12 get it done? I'm just curious.

13 MR. BENNER: Right now, I mean, we have  
14 two things that we could probably provide to the  
15 committee immediately. We had a public meeting with  
16 stakeholders on a body of reg guides and how we are  
17 looking to transition those from what they are now to  
18 what they are in the future.

19 Separately, a staff has been looking at  
20 the entire SRP, Standard Review Plan, and doing what  
21 we call SRP modernization. And in the area of digital  
22 I&C we've looked at the entire chapter and how we  
23 would reformat that chapter. We have a presentation  
24 on that that we've made internally for how we're doing  
25 SRP modernization.

1           So we could provide those two things right  
2 away.   Now, when we would have an information  
3 briefing, we could certainly negotiate with you as to  
4 when you would like such a briefing.

5           CHAIRMAN REMPE:   It's good to inform us,  
6 but I think it's more important to inform the  
7 applicants.

8           MEMBER KIRCHNER:   For new applicants is  
9 what I was thinking, advanced reactors.   The first  
10 blush, we've run into this.   There's this idea that  
11 LWR stuff doesn't apply to us, is not applicable, or  
12 it's too specific.   But in looking at your body of  
13 work, I have seen very little.   It's very technology  
14 neutral --

15          MR. BENNER:   Right.

16          MEMBER KIRCHNER:   -- or inclusive, I  
17 guess, is the right buzz word these days.   And so I  
18 think such an information road map would be invaluable  
19 for newcomers for advanced reactor designs.   We  
20 present it literally but I think you hear, oh, that's  
21 all -- 10 CFR Part 50 and 52, that's really not  
22 applicable to me because I've got a new design.

23                 But most of your work, I would think, from  
24 what we've seen is very technology inclusive.   So it  
25 would be a valuable document for new designs as well

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1 as the existing players.

2 MR. BENNER: Yes. In several forms we've  
3 had workshops with industry led by my staff that was  
4 mainly the operating fleet to talk about these  
5 changes. We've participated in a number of the  
6 advanced reactor activities, whether they were more  
7 general workshops or pre-application meetings with  
8 individual licensees.

9 We've tailored those discussions to what  
10 I would call the sophistication of the applicant. So  
11 we certainly don't have a one-size-fits-all  
12 presentation for those audiences, but we do as we have  
13 different avenues.

14 That's a little different than what we  
15 were thinking of as to one thing that explains all of  
16 this that we would share with any stakeholder. We  
17 found a lot more customization has been useful in the  
18 discussions we've had.

19 MEMBER KIRCHNER: I'm just thinking  
20 though, it would be a while before 53 -- if it becomes  
21 a rule, in the interim people are going to come to you  
22 under the banner of 50 and 52. So giving them a road  
23 map through the system will be very useful.

24 CHAIRMAN REMPE: Maybe a good place to  
25 start is to have a briefing with us, but you might end

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1 up at the end of the briefing with something that  
2 heavily encourages the staff to make this available to  
3 a broader audience.

4 Anyway, I think we're done with that  
5 additional comment. Did you want to talk to the folks  
6 out in the --

7 MEMBER BROWN: I was going to ask if there  
8 was anybody on the phone lines that would like to make  
9 a comment.

10 Hearing none, I turn it back over to you,  
11 Joy.

12 CHAIRMAN REMPE: Great. Thank you. Do  
13 you want to have a 15-minute break? We'll come back,  
14 if I did my math correctly, at ten 'til 3:00 on the  
15 East Coast time. We'll have someone bring your letter  
16 up and you can do a read-through. Does that sound  
17 good?

18 MEMBER BROWN: Um-hum.

19 CHAIRMAN REMPE: Okay. We're going to  
20 recess. We'll be back at ten 'til.

21 (Whereupon, the above-entitled matter went  
22 off the record at 2:34 p.m. and resumed at 2:54 p.m.)

23 CHAIRMAN REMPE: Okay. We are back in  
24 session.

25 Member Brown, would you read us your

1 letter?

2 MEMBER BROWN: Yes. Before I start I will  
3 give you an outline. Are you going to talk with Walt  
4 or do you want me to read?

5 CHAIRMAN REMPE: We'd like you to read.

6 MEMBER BROWN: Okay. Let me at least  
7 talk. This is an introduction of all the subjects  
8 that we covered, both in the subcommittee meeting and  
9 in this meeting. It's broken down into five items.

10 Can you all hear me?

11 PARTICIPANT: You've got to have it in  
12 front of you.

13 MEMBER BROWN: Yes, I know. I just yell  
14 at everybody.

15 I'll leave the whole thing. But before we  
16 go detailed, we ought to decide what we want to cover  
17 and what we don't want to cover. So let me read the  
18 whole thing and then I'll tell you when we're  
19 switching. And then we can figure out when I finish  
20 what to do or not do, okay? All right.

21 Subject, Proposed Draft Reg Guide 1.152  
22 Revision 4, Criteria for Programmable Digital Devices  
23 in Safety-Related Systems for Nuclear Power Plants.

24 Dear Mr. Dorman, During the 701st meeting  
25 of the Advisory Committee on Reactor Safeguards,

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1 November 29 through December 2, 2022, we reviewed  
2 Proposed Draft Regulatory Guide 1.152 Revision 4,  
3 Criteria for Programmable Digital Devices in Safety-  
4 Related Systems in Nuclear Power Plants.

5 Our Digital Instrumentation Controls  
6 Committee also reviewed this matter on November 17,  
7 2022. During this review we had the benefit of  
8 discussions with the representatives of the United  
9 States Nuclear Regulatory Commission. We also had the  
10 benefit of the documents referenced.

11 Conclusion and Recommendation. In  
12 general, we agree with the proposed revision, 1.152  
13 Revision 4, but it should not be issued for public  
14 comment until resolution of the five issues in the  
15 discussion have been incorporated into the reg guide.

16 Introduction. CFR 50.55a(h) (2) and (h) (3)  
17 mandate compliance with the requirements stated in  
18 IEEE Standard 279, various dates, and IEEE Standard  
19 603-1991, IEEE Criteria for Safety Systems for Nuclear  
20 Power Generating Stations for Post-1991 Safety System  
21 Applications and Development. These standards were  
22 written and applied for analog systems.

23 For applications for computer-based  
24 systems, Reg Guide 1.152 series endorsing IEEE  
25 Standard 7-4.3.2, IEEE Standard Criteria for



1 Programmable Digital Devices in Safety Systems of  
2 Nuclear Power Generating Stations, various dates, were  
3 developed and first issued in 1985. These standards  
4 use the term safety system, consistent with the NRC's  
5 definition --

6 (Whereupon, the above-entitled matter went  
7 off the record at 2:58 p.m. and resumed at 3:45 p.m.)

8 CHAIRMAN REMPE: Okay. We're back in  
9 session. At this point I'm going to ask Member  
10 Ballinger to lead us through the SHINE discussion.

11 MEMBER BALLINGER: Okay. I have one  
12 sentence. Who brought the champagne? I'll connect  
13 the dots. This is the last, we hope, meeting on the  
14 SHINE application. It's been a long, long process,  
15 but to my mind a rewarding one.

16 We'll have a presentation from the SHINE  
17 folks first and then from the staff. I think Josh is  
18 going to give a few words.

19 MR. BORROMEO: Yes. I have some quick  
20 opening remarks.

21 My name is Josh Borromeo. I'm Chief of  
22 the Non-Power Production and Utilization Facility  
23 Licensing Branch in the Office of Nuclear Reactor  
24 Regulation.

25 Today you'll be hearing an overview from

1 SHINE and the staff regarding the review of the SHINE  
2 Medical Technologies Operating Licensing Application.  
3 This is a first-of-a-kind review that required  
4 extensive coordination across the agency and required  
5 unique licensing approaches, which the staff will  
6 discuss today.

7 While the finalization of the staff's SER  
8 is a major milestone for the operating license for the  
9 SHINE facility, this is only part of the NRC's  
10 decision to issue the operating license. There are  
11 several inspection activities planned related to the  
12 construction and operational readiness of the facility  
13 that are required to be completed prior to the  
14 issuance of the license, and the staff will highlight  
15 those areas in the presentation today.

16 I want to thank ACRS for all the engaging  
17 interactions that we've had thus far. And I'm  
18 especially thankful for the flexibility that ACRS has  
19 extended to us as we had to make changes throughout  
20 the review.

21 And finally, I want to especially thank  
22 the NRC staff for all their diligent work on this  
23 challenging review and pushing it here to the finish  
24 line. So thanks.

25 MEMBER BALLINGER: Think we're ready to

1 go? Is it Catherine or Jeff?

2 MS. KOLB: Yes. My name is Catherine  
3 Kolb. I'll be giving the presentation for SHINE.  
4 Tracy was unfortunately unable to meet with us in  
5 person today.

6 MEMBER BALLINGER: You're going to have to  
7 be a little closer.

8 MS. KOLB: All right. Okay, got it.

9 So my name is Catherine Kolb. I'm the  
10 Senior Director of Plant Operations for SHINE. I'll  
11 be giving our presentation today. Tracy was unable to  
12 make it here in person.

13 We have an overview of the SHINE process.  
14 We'll start with the site overview, some status of the  
15 construction of our facility, an overview of the  
16 process which you've all seen before, and summaries of  
17 our technological approach and safety philosophy.

18 The SHINE facility, which was envisioned  
19 to produce medical isotopes, is located in Janesville,  
20 Wisconsin, about four miles south of the city center  
21 in the southern edge of the city. It is about two  
22 miles from Interstate 3990 and directly to the east of  
23 the Southern Wisconsin Regional Airport.

24 In the next slide here you'll see our site  
25 plan. The large building in blue in the middle is the

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1 main production facility. That is where the  
2 irradiation process and the chemical separation  
3 processes take place.

4 To the south is the storage building.  
5 That is primarily a warehouse, but it also contains  
6 maintenance areas and office areas.

7 To the east of the site is the material  
8 staging building. That is where we temporarily store  
9 waste prior to shipment off-site for disposal.

10 The green building to the north of that is  
11 the resource building. That houses support equipment  
12 for the main production facility, including boilers  
13 and a standby natural gas generator.

14 And then the very small building in yellow  
15 is the nitrogen purge system building or the N2PS  
16 building. That is a safety system that is used on a  
17 loss of off-site power.

18 Here is a rendering of what the completed  
19 campus will look like. You can see the main  
20 production facility in the center, to the left the  
21 storage building, the warehouse over on the right, and  
22 in the back the resource and material staging  
23 buildings.

24 In our next slide you'll see what they  
25 actually look like as of a couple of days ago. The

1 main production facility you can see we're still  
2 working on some of the architectural details, but the  
3 facility structure is essentially complete. Inside we  
4 are working on process equipment and mechanical,  
5 electrical, and plumbing auxiliary equipment, which we  
6 have pictures of in another couple of slides.

7 The resource building, the small building  
8 that has support equipment, is also constructed. And  
9 we are installing equipment inside of that. The  
10 storage building is upright, but we haven't started  
11 outfitting the inside of that to any great extent.

12 Here are some photos of inside the main  
13 production facility. On the left is a picture of  
14 workers installing process piping in the subgrade  
15 trenches. You can see some of the piping. It's the  
16 scaffolding there. We have approximately 50 percent  
17 of all the process piping installed and about 60  
18 percent of it welded out.

19 In the center picture, that yellow  
20 structure is actually a temporary crane that will be  
21 used to construct direct to the supercell. We have  
22 about half of the shipping containers containing the  
23 supercell pieces on-site, and we are beginning that  
24 installation there. We needed a temporary crane so  
25 that we can both construct the supercell and the areas

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1 to the right in the photo, which have the subgrade  
2 tanks and the other process equipment.

3 And finally, on the right is a photo of  
4 the radiological ventilation zone 2 air handling  
5 units. Those are part of the mechanical, electrical,  
6 and plumbing scope of which 50 percent is completed.

7 These are the support equipment and the  
8 auxiliary equipments mostly in the non-safety-related  
9 portions of the building. You can see some of the  
10 conduit, hangers, and lighting also installed in the  
11 overhead there, so that is also well underway.

12 The next couple of slides are just a brief  
13 overview of the SHINE process. The SHINE facility, if  
14 you start at number one there, is the target solution  
15 preparation area where we take depleted uranium metal,  
16 oxidize it, and dissolve it in sulfuric acid in order  
17 to form uranyl sulfate target solution. This is done  
18 only periodically in the life of the facility, mostly  
19 up front. And then that room is used for making make-  
20 up solution ongoing.

21 The target solution is directed into a  
22 hold tank, shown as number two there in the center of  
23 the rendering. From the hold tank the target solution  
24 is lifted by our vacuum and transfer system into the  
25 target solution vessel, which is the upright portion

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1 of the T-shaped vessel shown underwater in that pool.  
2 We fill to 95 percent by volume of criticality.

3 Then we irradiate for about five and a  
4 half days using the accelerator, which is the blue  
5 pressure vessel in the white box, where a beam of  
6 deuterium ions are directed into a tritium gas target  
7 which create a fusion reaction, which produces helium  
8 and neutrons which are used to fission the uranyl  
9 sulfate target solution. Of the fission products  
10 moly-99 is one of those, which is our main target  
11 isotope.

12 After about five and a half days, we drain  
13 the solution from the target solution vessel into the  
14 dump tank. We let the very short-lived fission  
15 products decay. Then we send the solution via the  
16 underground pipe trenches, which you saw in the  
17 previous picture, over to the supercell.

18 The solution is passed through an  
19 extraction column where the molybdenum adheres to the  
20 media. The bulk of the solution returns to the hold  
21 tank by the same underground pipe trenches. The  
22 extraction column is then washed.

23 The washes are directed into a waste tank,  
24 shown as number five in the photo. And the moly is  
25 then eluted off of the column, purified, tested for

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1 product quality, and packaged in the supercell.

2 So the technological approach of the SHINE  
3 facility is based on a couple of principles. Our  
4 systems are small. A maximum license power of 125  
5 kilowatts per unit, which is hundreds of times less  
6 power than reactors that are being used currently to  
7 produce medical isotopes.

8 The low source term helps ensure safety of  
9 the public and of our workers. The decay heat of the  
10 system produces less than one kilowatt within five  
11 hours after the end of the irradiation, so it requires  
12 no forced cooling. It is all passively cooled by the  
13 pool that you saw in the previous rendering.

14 The low size also minimizes the production  
15 of waste nuclides compared to reactors, which both  
16 need to irradiate to their target for making medical  
17 isotopes and their reactor fuel.

18 Our targets are usable, as we talked about  
19 in the last slide. The solution is irradiated,  
20 processed, and irradiated again. This reduces waste  
21 in this process. It's using uranium and making moly  
22 via fission. It produces high specific activity moly-  
23 99, which is completely compatible with the current  
24 supply chain for our customers. Using the LEU target  
25 solution also eliminates the need to use highly

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1 enriched uranium.

2 Our process is driven by a low-energy  
3 electrostatic accelerator, so it does not produce a  
4 self-sustaining critical reaction. It is driven by  
5 the accelerator. So if power is shut down, if the  
6 accelerator's shut down, the fission process  
7 eventually terminates, leading to an inherently safe  
8 design.

9 And finally, you saw in the previous slide  
10 there were many units. There are eight irradiation  
11 units in the facility and three processing trains  
12 within the supercell. Each unit can be directed to at  
13 least two different supercell processing trains, which  
14 provide operational skill ability and flexibility for  
15 our facility and allow us to more reliably manufacture  
16 products to deliver to our customers.

17 The safety philosophy of the SHINE  
18 facility -- this is my last slide to go over this --  
19 the system is designed to operate at low pressure/low  
20 temperatures as compared to some reactor designs. And  
21 it produces low decay heat, as I mentioned previously.  
22 This results in minimal stored energy when compared to  
23 alternatives, leading to essentially a safer facility.

24 The eight independent irradiation units  
25 are independent. They each have their separate and

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1 dedicated target solution reactivity protection  
2 system, a safety-related I&C system. So this design  
3 limits common cause failures between the eight  
4 irradiation units.

5 MEMBER BALLINGER: This is Ron Ballinger.  
6 I'm just curious as to -- how does that limit common  
7 cause failures? I mean, it seems to me that you could  
8 have common cause failures.

9 MEMBER KIRCHNER: You could have common  
10 cause in all eight.

11 MEMBER BALLINGER: Yes.

12 MS. KOLB: You could have the same cause  
13 in all of them because they all have the same design.  
14 I guess what we meant by this slide is no single  
15 failure. One failure would affect all eight units at  
16 the same time.

17 MEMBER BALLINGER: Right, okay. Thanks.

18 MS. KOLB: I apologize.

19 The third bullet there, operating --

20 MEMBER KIRCHNER: You could throw in the  
21 word redundant.

22 MEMBER BALLINGER: As opposed to -- yes.

23 MEMBER KIRCHNER: Yes.

24 MS. KOLB: When we present this again we  
25 will take that into consideration. I understand.

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1 Operator actions in our design are not  
2 required to mitigate the consequences of an accident.  
3 So operators are not required to do anything after a  
4 design-basis accident. The systems are designed to  
5 either automatically or passively handle the  
6 situations that they were designed for.

7 In the event of an upset condition, the  
8 safety-related I&C system initiates a shutdown of the  
9 system. There are two independent safety-related dump  
10 valves, which both open, each controlled by a separate  
11 division of the TRPS system. The solution is gravity-  
12 drained into a TSV dump tank, which is designed to be  
13 favorable geometry for all uranium concentrations.

14 And the hydrogen that's generated by the  
15 fission process is maintained below the lower  
16 flammability limits by our off-gas system blowers,  
17 which are powered from an uninterruptable power  
18 supply, a safety-related electrical system. So  
19 following the short amount of time that the blowers  
20 need to be powered from the safety-related UPS system,  
21 the plant is passively safe.

22 We've done calculations that 90 days  
23 without cooling of the solution results in a pool  
24 temperature rise that is not more than 13 degrees  
25 Fahrenheit.

1           And the nitrogen purge system is in place  
2           to sweep any hydrogen that is produced by a radiolysis  
3           from the various tanks in the facility and the dump  
4           tank after potential loss of off-site power and the  
5           loss of the blowers or other active systems.

6           And that is the end of our presentation.

7           MEMBER KIRCHNER: Is the UPS run time a  
8           proprietary number? I don't remember.

9           MR. BORROMEO: I believe the run time in  
10          the Chapter 8 tables are not proprietary.

11          MEMBER KIRCHNER: Just for the public  
12          record, how long can you run your off-gas system  
13          blowers before you switch over to nitrogen purge?

14          MS. KOLB: The blowers are required to run  
15          for five minutes, at which point they automatically --

16          MEMBER KIRCHNER: Five minutes?

17          MS. KOLB: Five minutes, yes, at which  
18          point they would come off the battery. And the  
19          nitrogen purge system would take over and provide the  
20          hydrogen mitigation function.

21          MEMBER KIRCHNER: Thank you.

22          MEMBER SUNSERI: Catherine, this is Matt.  
23          Just one question. You're in this stage because of  
24          the supply chain and delivery of the irradiation  
25          units. Do you have a sense for how that schedule is

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1 coming? Is the supply chain supporting your  
2 construction schedule or are they getting farther out,  
3 the delivery of the units?

4 MS. KOLB: I know that we have had some  
5 challenges with supply chain, particularly on  
6 commodity items. Most of our process equipment is on  
7 order or sitting in a warehouse. But some things like  
8 hangers and other normal commodities, the lead times  
9 have been getting longer.

10 MEMBER SUNSERI: Yes. The only reason I  
11 even mentioned that, just so you know what my  
12 relevance was, is just the longer that you have some  
13 operating units under construction -- just trying to  
14 minimize that in your objective as well.

15 MEMBER BALLINGER: We all set? Other  
16 members online?

17 CHAIRMAN REMPE: I have one just final  
18 comment because this may be the last time you're here.  
19 I think that all of us were very pleased to see the  
20 responsiveness of SHINE. The visit helped make things  
21 more concrete for us.

22 Again, I think that efficient regulation  
23 and review by ACRS really depends a lot on the  
24 applicant. And you guys did a great job. So thank  
25 you.

1                   MEMBER BALLINGER:   And I was mentally  
2                   processing those photos in the first few slides and  
3                   comparing it to the last time we were there, and  
4                   there's quite a different.       There's quite a  
5                   difference.   So thank you.

6                   I guess we're ready for the staff.   I  
7                   don't know.   Who's the presenter?

8                   MR. BORROMEO:   It'll be Mike Balazik.

9                   MR. BALAZIK:   Hi.   This is Mike Balazik.  
10                  Can everybody me okay?

11                  MEMBER BALLINGER:   Yes.

12                  MR. BALAZIK:   Okay.   We'll start here in  
13                  a second.   All right.

14                  Good afternoon, everyone.   My name is Mike  
15                  -- can you guys hear me okay?

16                  MEMBER BALLINGER:   I can.

17                  MR. BALAZIK:   Okay.   I'll go ahead.

18                  Good afternoon, everyone.   My name is Mike  
19                  Balazik.   I'm the Project Manager and Inspector in the  
20                  Non-Power   Production   and   Utilization   Facility  
21                  Licensing Plant in the Office of Nuclear Reactor  
22                  Regulation.   Today I'll be providing an overview of  
23                  the staff's review of the application, some background  
24                  information, and some upcoming next steps of the  
25                  process.

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1 Next slide, please.

2 NRC staff is committed to conducting  
3 efficient and effective reviews of applications and  
4 inspections in accordance with applicable regulatory  
5 requirements using appropriate regulatory guidance and  
6 acceptance criteria while ensuring the protection of  
7 the health and safety of the public.

8 NRC licensing and oversight activities  
9 support the US national security interest in nuclear  
10 nonproliferation policy objectives to establish a  
11 domestically available and reliable supply of  
12 molybdenum-99 without the use of highly enriched  
13 uranium.

14 The NRC licensing activities include  
15 initial licensing and subsequent license amendment  
16 requests for facilities proposing to manufacture,  
17 irradiate, and process low-enriched uranium and  
18 molybdenum targets. The NRC oversight activities  
19 include construction, inspection, operational  
20 readiness reviews, safety and security inspection, and  
21 licensing of operators.

22 Next slide, please.

23 The Division of Advanced Reactors and Non-  
24 Power Production and Utilization Facilities, otherwise  
25 known as DANU, has the lead responsibility for

1       licensing of non-power production and utilization  
2       facilities licensed under Part 50.

3               The following type of facilities can be  
4       licensed as a 103 facility, which is a commercial  
5       facility, or a 104 facility, which is for medical  
6       therapy and research and development facilities. Some  
7       of these facilities include non-power reactors,  
8       subcritical operating assemblies similar to what SHINE  
9       is, and production facilities. SHINE also contains a  
10      production facility.

11             NRR relies on lots of expertise for this  
12      type of review. We reached out to a lot of the other  
13      offices that have supported the review in the areas of  
14      emergency planning, physical security, accident  
15      analysis, crit safety, and cyber security.

16             Next slide, please.

17             Now to touch on some background  
18      information. The NRC received a two-part construction  
19      permit application, received an environmental report  
20      and a preliminary safety analysis report, otherwise  
21      known as a PSAR, back in 2013.

22             As mentioned earlier, SHINE is planning to  
23      produce molybdenum-99 from the fission of low-enriched  
24      uranium targets in an irradiation facility consisting  
25      of eight irradiation units. The molybdenum-99 is



1 recovered through the irradiated target solution  
2 processing in the radioisotope production facility,  
3 which consists of a series of hot cells.

4 The construction permit was issued on  
5 February 29th of 2016 and SHINE commenced construction  
6 of the facility back in September of 2019.

7 Next slide, please.

8 Now I'll touch upon the licensing  
9 overview. As mentioned earlier, the irradiation  
10 facility houses eight subcritical irradiation units.  
11 Catherine mentioned earlier that each one's licensed  
12 for 125 kilowatts.

13 So this is comparable in power level and  
14 safety considerations to existing non-power reactors  
15 licensed under 10 CFR Part 50. A majority of the  
16 reactors that are licensed are trigger reactors. I'd  
17 say most of those have a licensed power limit of  
18 approximately one megawatt.

19 What's different with SHINE is that SHINE  
20 operates -- it's a subcritical operating assembly, so  
21 it didn't meet the definition of a utilization  
22 facility as defined in 50.2. And it couldn't be  
23 licensed under 10 CFR Part 70.

24 So in order to align these processes with  
25 the potential hazards, the NRC issued a direct final

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1 rule. In chief, the 10 CFR 50.2 definition is to  
2 include the SHINE irradiation units.

3 So now in 50.2, under the definition of  
4 utilization facility it also includes an accelerator-  
5 driven subcritical operating assembly used for the  
6 irradiation materials containing special nuclear  
7 material, as described in the application assigned  
8 Docket No. 50-608, which is SHINE. This final rule  
9 was published in October of 2014. It became effective  
10 in December of 2014.

11 Next slide, please. Perfect.

12 Okay. So just to touch upon the licensing  
13 overview, the radioisotope production facility  
14 consists of a series of hot cells for molybdenum-99  
15 separation and purification. This facility was  
16 defined as a production facility based on the batch  
17 size, that the batches are greater than 100 grams. So  
18 it meets the definition under 10 CFR 50.24, Production  
19 Facility.

20 While the NRC has licensed production  
21 facilities in the past, there are no such facilities  
22 that are currently operating. There are a few  
23 facilities in the past that have conducted similar  
24 activities to SHINE.

25 There was the Cintichem, which was a five-

1 megawatt reactor. They did produce and process  
2 molybdenum-99. However, it was done under 10 CFR Part  
3 70 because the size of the batches were less than 100  
4 grams.

5 West Valley was a privately owned facility  
6 that was reprocessing fuel. So that was defined as a  
7 production facility. They ceased operation back in  
8 the early '70s. And I think Cintichem, they ceased  
9 their activities -- I think it was in 1990.

10 So this is the first production facility  
11 that's been licensed in quite some time. That's my  
12 point here.

13 Next slide, please. Thanks.

14 The safety reviews for operating license  
15 applications are conducted with the Commission's  
16 regulations. The main guidance that we use for this  
17 review was NUREG-1537, guidelines for preparing and  
18 reviewing applications for licensing of non-power  
19 reactors.

20 We also used the ISG. It expands the  
21 guidance for NUREG-1537 to include aqueous homogeneous  
22 non-power reactor technology and guidance for the  
23 production facilities for the separation of byproduct  
24 material from special nuclear material.

25 We also used standard industry guidance,

1 such as certain ANS standards and industry standards.  
2 These were documented in the Safety Evaluation Report.

3 Next slide, please.

4 I just want to touch upon the licensing  
5 process. For an operating license application, we  
6 accepted and of course documented the review. We  
7 performed the safety and environmental reviews. And  
8 also, we obtained information through a request for  
9 additional information and conducted audits to  
10 understand some of the underlying information.

11 So here today we're at the Advisory  
12 Committee on Reactor Safeguards review, so this has  
13 been going on since early this year where we presented  
14 the different chapters in the SER.

15 For hearings, there are no mandatory  
16 hearings required for an operating license. There is  
17 the potential for it to have a contested hearing. The  
18 staff did put out an FRN for the opportunity to  
19 request a hearing. That was issued back in January  
20 6th of 2020.

21 There were no hearing requests that were  
22 received. So the next step here is the decision to  
23 grant or deny the license, and I'll talk about that in  
24 a second here.

25 Next slide, please.

1 I just want to touch upon the license  
2 application itself real quick. SHINE submitted the  
3 license application in July of 2019.

4 SHINE requested a single operating license  
5 under Part 50. The irradiation units will be licensed  
6 as utilization facilities and the hot cells will be  
7 licensed as a production facility.

8 SHINE did request a 30-year license, a  
9 Class 103, which is a commercial license, per the  
10 requirements of 50.33, which requires general  
11 information in the application. And it states to  
12 request the duration of the license and what type of  
13 license it is.

14 SHINE did submit a supplement to the  
15 license application in January 2022. This was  
16 providing information with a phased approach to  
17 operation. The big picture consists of four phases of  
18 construction. The operation and construction will be  
19 occurring simultaneously.

20 The staff did evaluate the phased approach  
21 to operation that's documented in Appendix A of the  
22 Safety Evaluation Report. The staff's approach to  
23 this review was to look at the deltas between the full  
24 design and the phased approach design.

25 Next slide, please.

1           Here is a list of some of the interactions  
2           that the NRC staff has had with the subcommittee.  
3           Back in February we presented an overview of the  
4           review to the full committee. I'm just showing all  
5           the different interactions and the different  
6           information that was presented during the subcommittee  
7           meetings.

8           Next slide, please.

9           So now let me get to the basis for issuing  
10          of an operating license. The following findings must  
11          be made to issue an operating license. It's based on  
12          10 CFR 50.7.

13          These are that the constructions would  
14          substantially complete; the facility will operate in  
15          conformity with application regulations; reasonable  
16          assurance that operation will not endanger public  
17          health and safety; applicant technically and  
18          financially qualified; the provisions of Part 140 are  
19          satisfied, which is financial protection requirements;  
20          and issuance of a license will not be inimical to  
21          common defenses of security.

22          In the SER the staff has made a majority  
23          of these findings at the end of each chapter.  
24          However, for example, the construction has been  
25          substantially complete. As a result of oversight

1 activities, those findings will be made. So I guess  
2 I'll just say there's a lot more activity that needs  
3 to be done in the oversight space before an operating  
4 license is issued.

5 Also, the staff will have the operational  
6 readiness inspection, which is a tool to provide more  
7 input for NRC decisions regarding the issuance of an  
8 operating license.

9 Next slide, please.

10 So we'll talk about a couple of next  
11 steps. The staff plans to issue the Final Safety  
12 Evaluation Report. We do understand that there's the  
13 potential that as the facility moves towards  
14 substantially complete, there may be a need for design  
15 changes.

16 The staff will be ready to determine  
17 whether these design changes impact the informational  
18 findings in the SE, and potentially supplement the SE  
19 as needed. And of course we'll notify ACRS of any  
20 substantial changes to the SER.

21 Also, we're going to continue on with the  
22 construction oversight activities under Inspection  
23 Procedures 69020 and 69021. At this point we have  
24 issued three inspection reports related to  
25 construction oversight activities, which I've got

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1 documented there.

2 Next slide, please.

3 The NRC staff is developing a SHINE-  
4 specific inspection plan using Inspection Procedure  
5 69022, which is Inspections for Operational Readiness  
6 During Construction in Non-Power Production and  
7 Utilization Facilities. What I've got listed on the  
8 screen are some of the areas that we are planning to  
9 perform inspections. There may be more added later  
10 on, but this is what we're at least starting off with.

11 Also, the operational readiness  
12 inspections. We'll conduct these inspections once  
13 SHINE informs the NRC that they're ready for each  
14 inspection activity.

15 The final slide is that SHINE is expected  
16 to notify the NRC in writing when the construction of  
17 the facility is substantially complete. In our  
18 inspection activities we'll support the basis on the  
19 10 CFR 50.57 findings are satisfied, which allow  
20 issuance of the operating license.

21 That's my last slide. I don't know if  
22 there's any questions that I can answer.

23 MEMBER KIRCHNER: Mike, this is Walt  
24 Kirchner. Have you found any major design changes  
25 that would impact materially your SER?



1 MR. BALAZIK: No, not at this point.  
2 There have been some design changes throughout the  
3 review. One of the changes was related to the carbon  
4 delay beds and changing sensors, but there haven't  
5 been any substantive design changes. Most of them are  
6 minor.

7 However, going forward there's that  
8 potential that there may be substantive design  
9 changes. Right now we're just not knowing until the  
10 facility is substantially complete.

11 MEMBER KIRCHNER: Can you give us an idea  
12 of an estimated schedule for issuance of the operating  
13 license?

14 MR. BALAZIK: I think I would let SHINE  
15 answer that question based upon their construction  
16 schedule.

17 MR. BARTELME: This is Jeff Bartelme,  
18 Director of Licensing from SHINE. We are working  
19 through some schedule updates right now. We do have  
20 construction going through the majority of next year,  
21 but we're still working through an update. We're  
22 committed to getting the staff a letter in the near  
23 term providing a schedule update.

24 MEMBER BALLINGER: This is Ron Ballinger.  
25 I guess for the staff it's probably a bit subjective,

1 but is there a threshold for which you need to modify  
2 the SER? In other words, what constitutes enough  
3 change so that you would have to modify the SER and  
4 then maybe come before ACRS?

5 MR. BALAZIK: I think it's just dependent  
6 upon what we've got documented in there, if it would  
7 impact a finding. I think under that circumstance  
8 that we'd have to come back to the ACRS. I think  
9 we're going to have to do this as we see these design  
10 changes and make that determination.

11 And of course, we can share all design  
12 changes to the ACRS. It's just for their knowledge.  
13 But again, I think it just depends on how we've  
14 documented the design in the safety evaluation itself.

15 MEMBER BALLINGER: So it is a bit  
16 subjective? There's no manual anywhere that says if  
17 this happens then you have to do this?

18 MR. BALAZIK: That's correct.

19 MEMBER SUNSERI: This is Matt. They are  
20 using a 50.59-like process, right, a 50.59 or a 50.59-  
21 like process, aren't they?

22 MR. BALAZIK: They are --

23 PARTICIPANT: Is it for construction?

24 MR. BALAZIK: SHINE is using that for  
25 modifications for the facility.

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1           MEMBER SUNSERI: Right. I would think at  
2           least one threshold would be anything that didn't  
3           screen past 50.59 and required NRC approval prior to  
4           implementing would be one that you would want to bring  
5           forward.

6           MR. BORROMEO: This is Josh Borromeo. I  
7           think the ultimate threshold is if they make a design  
8           change and we're not aware of it. And then when we go  
9           to make our 50.57 finding, if it doesn't align with  
10          the FSAR, they don't get an operating license.

11          That's the ultimate backstop. Anything  
12          that goes to that level, they'll have to address their  
13          FSAR and we'll have to address our SE so that they are  
14          in alignment and we can issue the license.

15          MEMBER BALLINGER: So how does this  
16          process interact with the finding of substantially  
17          complete construction?

18          MR. BORROMEO: SHINE will notify the staff  
19          when they believe that they are substantially complete  
20          with the facility. And then we'll inspect to ensure  
21          that the facility is built in conformance with the  
22          FSAR and we'll be able to operate it in conformance  
23          with the FSAR. If we can't come to that finding, then  
24          we won't issue an operating license.

25          MR. BALAZIK: One of the modules in the

1 Operational Readiness Inspection Program are design  
2 changes. So that's where we can get a look at all  
3 those if needed.

4 MEMBER BALLINGER: Thank you.

5 Questions from the members? I'm not sure  
6 who's online anymore.

7 MR. BALAZIK: Thank you, everyone, for  
8 your time.

9 MEMBER BALLINGER: I hear no other  
10 questions.

11 Is it appropriate for public comments?

12 CHAIRMAN REMPE: Yes.

13 MEMBER BALLINGER: Okay. So now we should  
14 ask for public comments. If there are members of the  
15 public that would like to make a comment, please  
16 unmute yourself, state your name, and make your  
17 comment.

18 This is a bit anti-climatic. Hearing  
19 none, we're through with the presentations.

20 I'm sure that I speak for the rest of the  
21 committee that we, if you can use the word, enjoyed  
22 the review process. And we thank you very much for a  
23 very thorough, both the staff and the applicant -- I  
24 don't think we ever found any question that we didn't  
25 get an answer to very quickly. Again, it sounds a bit

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1 anti-climatic but thank you.

2 Madam Chairman?

3 CHAIRMAN REMPE: Thank you for your  
4 leadership and getting us through that timely.

5 At this time, I'd like to ask the court  
6 reporter to close the record for the transcript and  
7 come back tomorrow at 8:30. Okay, Allegra?

8 COURT REPORTER: Yes.

9 CHAIRMAN REMPE: We're going off the  
10 record.

11 (Whereupon, the above-entitled matter went  
12 off the record at 4:24 p.m.)

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## Advisory Committee on Reactor Safeguards

# SHINE Medical Technologies, LLC Operating License Application Review

**Michael F. Balazik, Project Manager/Inspector**

Non-Power Production and Utilization Facility License Branch

Division of Advanced Reactors and Non-power Production and Utilization  
Facilities

Office of Nuclear Reactor Regulation

U.S. Nuclear Regulatory Commission

November 29, 2022

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# Supporting Domestic $^{99}\text{Mo}$ Production

- NRC staff committed to efficient reviews of applications and inspections in accordance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR)
- Licensing and oversight activities support U.S. national security interests and nuclear nonproliferation policy objectives of establishing a domestically-available and reliable supply of molybdenum-99 ( $^{99}\text{Mo}$ ) without the use of highly-enriched uranium
- Applications include initial license and license amendment requests for facilities proposing to manufacture, irradiate, and process low enriched uranium and molybdenum targets
- Oversight activities focused on construction inspection of utilization and production facilities

---

# Responsibilities and Coordination

- The Division of Advanced Reactors and Non-Power Production and Utilization Facilities (DANU) is responsible, in part, for initial licensing activities associated with NPUFs licensed under 10 CFR Part 50.
- The following types of facilities may be licensed as commercial or research and development facilities under Sections 103 or 104 of the Atomic Energy Act, respectively:
  - Non-Power Reactors, including advanced reactor technologies
  - Subcritical Operating Assemblies
  - Production Facilities
- NRR relies on the expertise and support of other offices in the following technical areas to review medical radioisotope facility applications:
  - Emergency Planning
  - Physical Security
  - Environmental
  - Financial Qualifications
  - Material Control and Accounting
  - Accident Analysis
  - Chemical safety
  - Criticality Safety
  - Cybersecurity



---

# SHINE Medical Technologies Background

- NRC received two-part construction permit application
  - Environmental Report (March 26, 2013)
  - Preliminary Safety Analysis Report (May 31, 2013)
- SHINE proposes to produce  $^{99}\text{Mo}$  from the fission of low enriched uranium target solution in an Irradiation Facility consisting of 8 irradiation units
- $^{99}\text{Mo}$  is recovered through irradiated target solution processing in a Radioisotope Production Facility consisting of hot cells
- Construction permit issued on February 29, 2016
- Construction commenced in September 2019

---

# Licensing Overview: SHINE Irradiation Facility

- Irradiation facility houses eight subcritical irradiation units, which are comparable in power level and safety considerations to existing non-power reactors licensed under 10 CFR Part 50
- However, due to subcriticality, irradiation units did not meet the existing definition of utilization facility in 10 CFR 50.2 and could not be licensed under 10 CFR Part 70
- To align licensing process with potential hazards, NRC issued direct final rule modifying 10 CFR 50.2 definition of utilization facility to include SHINE irradiation units
  - Published October 17, 2014
  - Effective December 31, 2014

---

## **Licensing Overview:**

# **SHINE Radioisotope Production Facility**

- Radioisotope Production Facility consists of a series of hot cells for  $^{99}\text{Mo}$  separation and purification
- Based on batch size (i.e., greater than 100 grams), facility meets the definition of a production facility as defined in 10 CFR 50.2, “Definitions”
- While the NRC has historically licensed production facilities, no such facilities are currently operating
- Few previously-licensed facilities have conducted similar activities as SHINE
  - Cintichem (licensed under 10 CFR Part 70)
  - West Valley (licensed as a reprocessing facility)



---

# NRC Safety Review Methodology

- Safety reviews for operating license applications conducted in accordance with Commission's regulations
- Staff's review tailored to unique and novel technology described in operating license application using appropriate regulatory guidance
  - NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors"
  - Interim Staff Guidance Augmenting NUREG-1537
  - Other guidance (e.g., regulatory guides and industry standards) and engineering judgment used, as appropriate

---

# 10 CFR Part 50 Licensing Process

- Review process for operating license applications:
  - Acceptance and docketing review
  - Parallel safety and environmental reviews
  - Request(s) for additional information, as needed
  - Advisory Committee on Reactor Safeguards (ACRS) review
  - Hearing(s)
    - No mandatory hearing required for an operating license
    - Potential for contested hearing(s)
    - Opportunity to request hearing and petition for leave issued on January 6, 2020 (60 days)
    - No hearing requests received
  - Decision to grant or deny license

---

# SHINE Operating License Application

- SHINE submitted operating license application on July 17, 2019
- SHINE requested a single operating license under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities”
  - Irradiation units licensed as *utilization facilities*
  - Hot cells licensed as *production facility*
- SHINE requested a 30-year (Class 103) license (ML19211C089)
  - Per 10 CFR 50.22, Class 103 license is for commercial or industrial activities
  - Per 10 CFR 50.51(a), states that each license will be issued for a fixed period of time to be specified in the license but in no case to exceed 40 years from date of issuance
- SHINE submitted a supplement to the license application in January 2022, providing information on phased approach to operations
  - Consists of four phases
  - Operations and construction occurring simultaneously
  - The staff’s evaluation of phased approach to operations is documented in Appendix A of the safety evaluation report (SER)

---

# ACRS Subcommittee Engagement

- Subcommittee Topics (March 17)
  - Facility Description (Chapters 1, 4)
  - Site Characteristics (Chapter 2)
  - Coolant Systems (Chapter 5)
  - Engineered Safety Features (Chapter 6)
- Subcommittee Topics (May 6)
  - Design of Structures, Systems, and Components (Chapter 3)
  - Electrical Power Systems (Chapter 8)
  - Auxiliary Systems (Chapter 9)
  - Radiation Protection and Waste Management (Chapter 11)
- Subcommittee Topics (May 17/18)
  - Emergency Planning (within Chapter 12)
  - Accident Analysis (Chapter 13)
  - Criticality Safety (within Chapter 6b)
  - Material Control and Accounting (within Chapter 12)
- Subcommittee Topics (July 19/20)
  - Design Criteria (within Chapter 3)
  - Instrumentation and Control (Chapter 7)
  - Fire Protection (within Chapter 9)
  - Conduct of Operations (within Chapter 12)
  - Operator Training (within Chapter 12)
  - Human Factors Engineering (within Chapter 7)
- Subcommittee Topics (September 9, 2022)
  - Technical Specifications (Chapter 14)
  - Cybersecurity (within Chapter 12)
- Subcommittee Topics (October 21, 2022)
  - Process Integrated Control System (within Chapter 7)
  - Phased Startup Operations (within Appendix A)

---

# Basis for Issuing Operating License

- The following findings must be made to issue an operating license, based on 10 CFR 50.57, “Issuance of operating license.”
  - Construction has been substantially completed [10 CFR 50.57(a)(1)]
  - Facility will operate in conformity with application and regulations [10 CFR 50.57(a)(2)]
  - Reasonable assurance that operation will not endanger public health and safety [10 CFR 50.57(a)(3)]
  - Applicant technically and financially qualified [10 CFR 50.57(a)(4)]
  - Provisions of 10 CFR Part 140 satisfied (Financial Protection Requirements) [10 CFR 50.57(a)(5)]
  - Issuance of license will not be inimical to common defense and security [10 CFR 50.57(a)(6)]
- These findings are supported by the NRC staff’s evaluation of the application, as documented in the SER, and the staff’s oversight activities, as documented in inspection reports
- Operational readiness inspection is a tool to provide input for NRC decisions regarding the issuance of an operating license



---

# Next Steps

- The NRC staff will issue the final safety evaluation report
- If there is a need for design changes prior to the facility being substantially complete
  - Determine whether design change impacts the information and findings in the SER
  - Supplement the SER, as needed
  - Notify ACRS of any substantive changes to the SER
- Construction inspection oversight continues under IMC 69020, “Inspections of Safety-Related Items (and Services) During Construction of Non-Power Production and Utilization Facilities” and IMC 69021, “Inspection of Quality Assurance Program Implementation During Construction of Non-Power Production and Utilization Facilities”
  - Inspections completed: May 2022 (ML22154A405), April 2021 (ML21224A127), December 2019 (ML20030A744)

---

## Next Steps (continued)

- NRC staff is developing a SHINE facility specific inspection plan using Inspection Procedure (IP) 69022, “Inspections of Operational Readiness During Construction of Non-Power Production and Utilization Facilities”

Process and Effluent Monitoring	Criticality Safety
Radiation Protection	Start-up Plan for Operation
Operator Training Requalification	Transportation
Emergency Preparedness	Instrumentation and Control
Operations Quality Assurance	Physical Security and Cybersecurity

- Operational readiness inspections will be conducted once SHINE informs the NRC of readiness for each inspection activity

---

## Next Steps (continued)

- SHINE is expected to notify the NRC in writing when construction of the facility is substantially complete
- Inspection activities will support the basis for the NRC's conclusion that the 10 CFR 50.57 findings are satisfied



# Overview of the SHINE Medical Isotope Production Facility (Open Session)

TRACY RADEL, VICE PRESIDENT OF ENGINEERING

# Outline

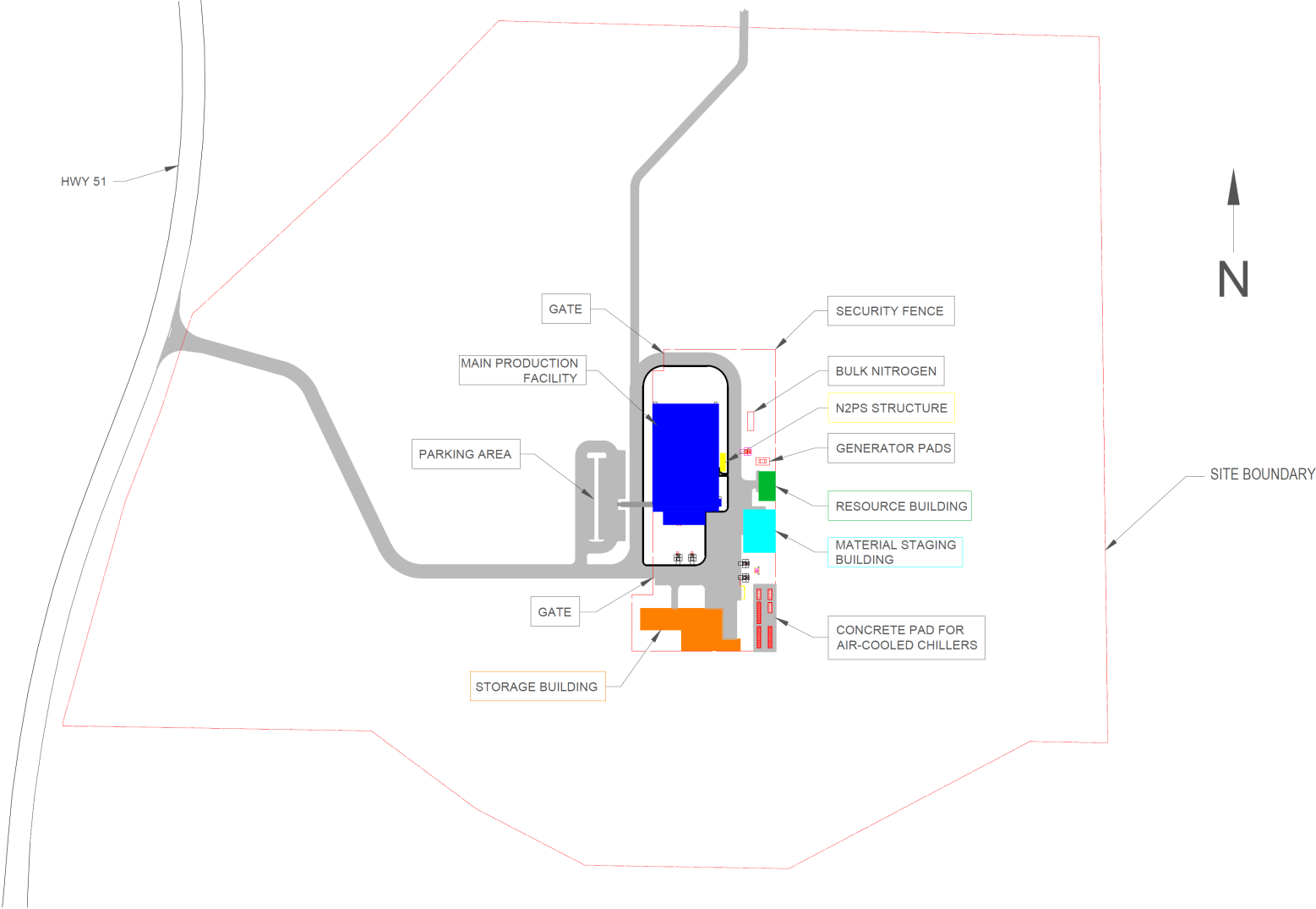
- SHINE Site Overview
- Construction Status
- Process Overview
- Technological Approach
- Safety Philosophy



# Located in Janesville, WI



# Site Plan





# Site Rendering





# Construction Status

Main Production Facility



Resource Building



Storage Building





# Construction Status



Process Piping



Crane Structure for Installation of Supercell

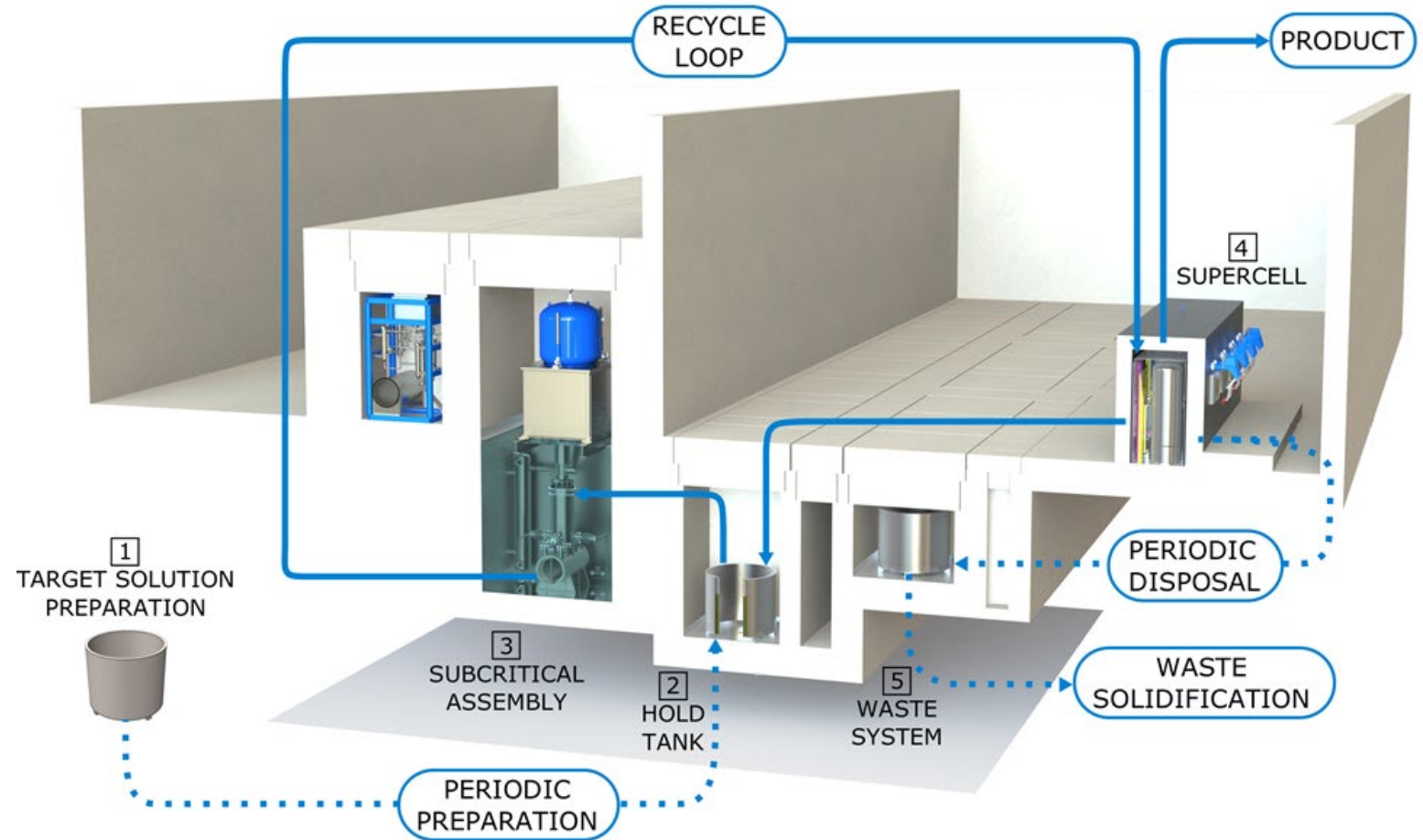


Air Handling Units



# Process Overview

- Periodic solution preparation from LEU
- Solution chemistry check and staging
- Irradiation for 5.5 days
- Extraction, purification, QC, and packaging
- Waste handling



# Technological Approach

- Small systems: 125 kW, hundreds of times less power than isotope production reactors being used
  - Low source term—helps ensure safety of public and workforce
  - Decay heat per system < 1 kW within 5 hours
  - Minimizes waste nuclide generation compared to reactors
- Low enriched uranium (LEU) reusable target
  - Reduces waste
  - Product compatible with current supply chain
  - Eliminates need for highly enriched uranium (HEU)
- Driven by low-energy electrostatic accelerator
  - Fission essentially terminate shortly after driver turned off
- Multiple units and trains provide operational scalability and flexibility

# Safety Philosophy

- Low decay heat, low pressure, low temperature system
  - Minimal stored energy
- Independent units limit common cause failures
- Operator actions are not required to mitigate the consequences of an accident
- In the event of an upset condition:
  - Target solution vessel (TSV) reactivity protection system (TRPS) initiates trip of system
  - Two completely independent safety-related TSV dump valves open
  - Target solution gravity drains to the TSV dump tank (safe for all uranium concentrations)
  - Hydrogen concentration maintained below lower flammability limit (LFL) by off-gas system blowers
- Following uninterruptible power supply (UPS) battery run time, entire plant is passively safe
  - 90 days without cooling: pool temperature rise is not more than 13°F
  - Nitrogen purge system for hydrogen control



# **Draft Guide 1374 - Proposed RG 1.152, Revision 4**

## **Criteria for Programmable Digital Devices in Safety-related Systems of Nuclear Power Plants**

**Advisory Committee on Reactor Safeguards  
Digital Instrumentation & Controls Systems Full Committee Briefing  
November 29, 2022**

# Working Group

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  - Richard Stattel
- **NRR/DORL**
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- **RES/DE**
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  - Paul Rebstock
- **NSIR/DPCP**
  - Ismael Garcia
  - Kim Lawson-Jenkins

# Presentation Outline

- Scope of Draft Guide (DG) 1374 and associated Regulatory Guide (RG) 1.152, Rev. 4
- Background
- Proposed Changes
- Subcommittee Feedback and Staff Responses
- Summary
- Q&A



# Scope of DG 1374 & RG 1.152, Rev. 4

Endorses IEEE Std. 7-4.3.2-2016 as an acceptable approach to meet regulatory requirements for promoting high functional reliability, design quality, and a Secure Development and Operational Environment (SDOE) for the use of programmable digital devices (PDDs) in the safety-related systems of nuclear power generating stations.

# Background

- Major Changes in IEEE Std 7-4.3.2 – 2016:
  - Incorporating secure development and operational environment guidance from RG 1.152, revision 3.
  - Providing specific criteria on the use of software tools in digital devices and the development of hardware, software, firmware, and programmable logic.
  - Revising Annex D, “Identification and Control of Hazards.”

# Proposed Changes

- Remove SDOE guidance from RG 1.152, R3 that has been incorporated into IEEE Std 7-4.3.2-2016.
- Endorse Revision 2016 of IEEE Std 7-4.3.2 with exceptions and clarifications, including:
  - Additional guidance for fault detection and self-diagnostics, if used, in DI&C systems.
  - Guidance and clarification for control of access.
  - Endorsement of Annex D, ““Identification and Control of Hazards.”
  - Include additional guidance for providing safeguards to safety-related programmable digital devices before installation.

# Subcommittee Feedback and Staff's Responses

## Feedback #1

DG-1374 does not contain guidance addressing external electronic data communication control of access.

## Response

The staff will revise DG-1374 to provide an example indicating the use of hardware-based uni-directional communication is an approach the staff considers acceptable.

# Subcommittee Feedback and Staff's Responses (Cont.)

## Feedback #2

The guidance for measurement and test equipment (M&ET) in IEEE Std 7-4.3.2 only requires disabling of wireless capability prior to connecting to safety-related equipment.

## Response

Significant guidance exists for both the control of M&TE and use of wireless technologies. IEEE Std 7-4.3.2 additionally requires that portable M&TE be maintained, controlled and accessed in a secure location with access limited to authorized personnel only. Additionally, RG 5.71 contains the following guidance:

- Section C.4.2 states “checking and documenting all media and mobile devices, such as laptops, containing diagnostic, CDA [critical digital assets], and system and test programs or software for malicious code before the media or mobile device is used in or on a CDA.”
- Section B.1.17 states that the licensee/applicant is responsible for: establishing usage restrictions and implementation guidance for wireless technologies, documenting, justifying, authorizing, monitoring, and controlling wireless access to CDAs, and conducting scans for unauthorized wireless access points.

The staff believe these controls remain adequate and does not intend to incorporate additional guidance into RG 1.152.

# Subcommittee Feedback and Staff's Responses (Cont.)

## Feedback #3

The endorsement status of IEEE Std 7-4.3.2 Annex C, “Dedication of Existing Commercial Computers,” is not clear.

## Response

- The staff reviewed Clause 5.17 of IEEE 7-4.3.2 and found that it provides an acceptable approach for performing commercial grade dedication of digital equipment in safety-related systems at nuclear power plants. The staff also finds that Clause 5.17 is not in conflict with the guidance in RGs 1.164 and 1.250; therefore, the staff proposes endorsement of Clause 5.17.
- The staff will revise the draft guide to clarify that Clause 5.17 of IEEE Std 7-4.3.2-2016 provides criteria that the NRC staff finds acceptable for the use of commercial digital equipment in safety-related systems at nuclear power plants. Clause 5.17 references Annex C for additional information on commercial grade item acceptance and dedication. However, while there is useful historical and reference information in Annex C, the NRC staff does not see a need to endorse such information.

# Subcommittee Feedback and Staff's Responses (Cont.)

## Feedback #4

DG-1374 does not contain the discussion of the I&C safety system architecture, including the fundamental design principles.

## Response

The scope of RG 1.152 is to endorse IEEE Std 7-4.3.2 as an acceptable approach to meet regulatory requirements (IEEE Std 603).

I&C safety system architecture is evaluated by the staff in the context of meeting four fundamental design principles: redundancy, independence, deterministic, and diversity and defense-in-depth (D3). The staff performs its evaluation using its licensing process guidance contained in Interim Staff Guidance (ISG) 06 and the Design Review Guide (DRG).

While the fundamental design principles are considered by the staff when evaluating the I&C safety system architecture, deterministic and D3 are not part of IEEE Std 603 requirements and thus are out of scope for this RG.

# Summary

- RG 1.152 is one of the primary RGs used by applicants and licensees in the development of digital I&C license applications, reactor certifications, and digital I&C topical reports.
- The update to RG 1.152 is a high priority based on recent licensing experience and interactions with stakeholders that contributed to the update to IEEE Std 7-4.3.2 in 2016.



## Summary (Cont.)

The staff proposes the revision of RG 1.152 to

- Update information and guidance in the areas of functional reliability, design quality, and a SDOE for programmable digital devices in the safety-related systems of nuclear power plants.
- Support NRC guidance and review practices.
- Ensure that the guidance in these areas is current and consistent with the staff's position.

Thus, enhancing the efficiency and effectiveness of licensing review.

# Questions?