

# **Official Transcript of Proceedings**

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SHINE Subcommittee

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UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON REACTOR SAFEGUARDS  
(ACRS)

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SHINE SUBCOMMITTEE

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WEDNESDAY

JULY 20, 2022

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The Subcommittee met via Teleconference,  
at 9:30 a.m. EDT, Ronald G. Ballinger, Chairman,  
presiding.

COMMITTEE MEMBERS:

RONALD G. BALLINGER, Chairman

VICKI M. BIER, Member

CHARLES H. BROWN, JR. Member

VESNA B. DIMITRIJEVIC, Member

GREGORY H. HALNON, Member

JOSE MARCH-LEUBA, Chairman

DAVID A. PETTI, Member

JOY L. REMPE, Member

MATTHEW W. SUNSERI, Member

1 ACRS CONSULTANTS:

2 DENNIS BLEY

3 STEPHEN SCHULTZ

4  
5 DESIGNATED FEDERAL OFFICIAL:

6 CHRISTOPHER BROWN

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

(9:30 a.m.)

CHAIRMAN BALLINGER: Good morning, everyone. This is the second day of the meeting of the SHINE Subcommittee of the Advisory Committee on Reactor Safeguards. I'm Ron Ballinger, chairman of today's subcommittee meeting. Today's meeting is an extension or a continuation, if you will, of yesterday's meeting.

Members present so that I'll be clear are myself, Charlie Brown, Charles Brown, Vicki Bier, Dave Petti, Greg Halnon, Jose March-Leuba, Matt Sunseri, Vesna Dimitrijevic, and our consultants, Dennis Bley and Stephen Schultz. If I have missed anybody, I apologize.

Today, we will be covering the following topics, operator training and requalification, human factors, conduct of operations, a startup plan, and any other loose ends that we might find that we need to discuss by the end of the day.

So, with that, are there any members or consultants that wish to bring up a topic that we discussed yesterday but might need further clarification? Okay, thank you. So, Josh, I understand that you're going to make a few comments?

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1 MR. BORROMEO: I don't have anything in  
2 addition to what I said yesterday, so we can move onto  
3 SHINE.

4 CHAIRMAN BALLINGER: Okay, okay, great.  
5 So, the first presentation is the SHINE presentation  
6 on operator training and requalification, and I see  
7 the slides are up, so we're off and running. Thank  
8 you.

9 MR. WALLER: All right, good morning,  
10 everyone, and thank you for taking the time to let me  
11 present our operator training program. My name is  
12 Brent Waller and I am the training manager for SHINE.

13 First, we'll talk about our initial  
14 training program which actually starts before a  
15 candidate ever shows up. We have to select the  
16 candidates that would be appropriate for our training  
17 program.

18 The guidance that we use is ANSI-15.4-  
19 2016, selection and training of personnel for research  
20 and test reactors. We use that as the screening  
21 process during our hiring to make sure that candidates  
22 have the requisite background and experience to enter  
23 for the role that they are coming in, for example,  
24 licensed operator or senior licensed operator, and our  
25 medical screenings that we conduct are also per ANSI-

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1 15.4-2016.

2           Upon identifying a candidate that we  
3 believe meets the requirements of ANSI-15.4-2016, they  
4 are enrolled in our initial training program. Our  
5 initial training program has a couple of phases. The  
6 first phase is the fundamentals phase. That includes  
7 topics that you would expect to be covered in a  
8 fundamentals type training program.

9           Examples of topics would include  
10 thermodynamics, heat transfer and fluid flow, nuclear  
11 theory and kinetics, and also includes components of  
12 training such as electrical components, sensors, that  
13 kind of thing, and then we also have a couple of  
14 topics that are unique to SHINE's application, for  
15 example, plasma physics.

16           We also have a radiation protection and  
17 administration requirements phase. That program goes  
18 into more detail about radiation protection  
19 principles, for example, calculating dose rates,  
20 shielding, that kind of stuff.

21           And then we also have an administrative  
22 requirements phase. That covers administrative topics  
23 relevant to licensed operators. That would include  
24 things like configuration management, conductive  
25 operations, and technical specifications.



1           We then go into a systems phase where we  
2           then teach the operators the systems that are in the  
3           SHINE facility, both safety related and non-safety  
4           related systems.

5           It then progresses into a plant evolutions  
6           phase. That includes our normal, abnormal, and  
7           emergency operating procedures, and that's also where  
8           the candidates have dedicated on-the-job training  
9           guides that they would be in the plant performing  
10          evolutions for their qualification.

11          We follow that up with an exam preparation  
12          phase to get our candidates ready to take the NRC  
13          written and operating exam, and then for those  
14          candidates designated as senior licensed operators, we  
15          have an additional supervisory training element to  
16          that.

17          For our initial program examinations, we  
18          follow the requirements of ANCI-15.4, which has a  
19          passing criteria of 70 percent. Any candidates that  
20          scores less than that 70 percent on our internal  
21          examination has to go through a remediation process  
22          and a reexamination process.

23          Examinations are good for checking of  
24          knowledge items. For performance items, we have on-  
25          the-job evaluations that are used for their

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1 performance test. That coincides with their on-the-  
2 job training session.

3 And then we have the option in our program  
4 to use oral exams as needed to do level of knowledge  
5 checks of individuals or groups. We can also use it  
6 as an alternative in case we have to go through a  
7 deeper remediation.

8 As far as the contents of the initial  
9 license training program, they come from several  
10 sources. So, 10 CFR Part 55 lists several topics to  
11 be covered in the initial program. We cover all of  
12 those that are applicable to the SHINE design.

13 ANCI-15.4-2016 also provides some  
14 additional guidance and they are incorporated.  
15 Chapter 12, Section 10 of the FSAR has some topics  
16 delineated that are also covered, and then any  
17 additional topics that are determined by the systems  
18 approach to training that would be in addition to  
19 those listed above.

20 MEMBER SUNSERI: Hey, Brent, this is Matt  
21 Sunseri, just a question and a comment, or a comment  
22 and a question I should say. I realize you pulled the  
23 cut score of 70 percent from the reg guide.

24 It's my experience that the nuclear  
25 industry has moved away from 70 percent as the cut

1 score, especially when you use the systematic approach  
2 to training which is supposed to be a higher level of  
3 preparation for the candidates, and they really use 80  
4 percent as a good industry standard now. Did you give  
5 any thought to that or --

6 MR. WALLER: Yes, so the difference  
7 between 70 and 80 percent is, as someone who comes  
8 from a commercial power plant background as well,  
9 commercial power regs and INPO accredited training,  
10 they all drive you towards an 80-percent standard.

11 When you look at the NUREGs and ANSI  
12 standards that are invoked for research and test  
13 reactor and production facilities, they all reference  
14 a 70-percent standard. And while we use 70 percent as  
15 the programmatic standard, we have internal controls  
16 that we take for candidates that are scoring or  
17 trending less than an 80 percent.

18 MEMBER SUNSERI: Yeah, I understand that.  
19 I mean, you can see the optics though as a commercial  
20 facility if you're, you know, passing your operators  
21 at a C level versus a B level. It might, you know,  
22 just create some optics. Anyway, it's just a comment.  
23 I mean, I know you're meeting the regulations.

24 And then my question, or, yeah, that was  
25 a comment, and the question I have is back on your

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1 fundamentals preparation. Is it your intention to  
2 have your candidates sit for the generic fundamentals  
3 exam offered by the NRC or is that too much outside of  
4 the analysis of your systematic approach to training?

5 MR. WALLER: Yeah, so that's a good  
6 question. The generic fundamentals exam by regulation  
7 is unique to power plants when you look at the  
8 research and test reactor standards, including NUREG  
9 1478.

10 The fundamentals portion as administered  
11 by the NRC is not required, and in some cases, would  
12 be detrimental to how we want to train our operators.

13 The nuclear theory topics specifically  
14 focus a lot on critical operations with a nuclear  
15 theory behind that where we are a subcritical facility  
16 and our concerns were the operations. Their knowledge  
17 are in a different area.

18 So, it's not really a good fit and would  
19 provide mostly probably some negative training value  
20 if we were to use the GFE as-is, and we also know that  
21 the NRC on the power plant side is getting away from  
22 administering the GFE anyway.

23 MEMBER SUNSERI: Yeah, okay, all right,  
24 that's a fair response. I would just -- you know, I  
25 don't disagree with what you just said. I would

1 maybe, caution is too strong a word, but don't  
2 underestimate the value of having your operators  
3 understand critical operations.

4 I mean, they're going to be operating at  
5 the subcritical, but they need to understand what  
6 crossing that line is and what a critical reactor  
7 looks like so they can recover from that if necessary.

8 It's kind of like a pilot. You don't ever  
9 want to stall your airplane, but you better darn sure  
10 know how it approaches and what it does when it does  
11 stall. Anyway, that's my comment.

12 MR. WALLER: Yeah, so that is a good, good  
13 point, and all of our operators, they do have to pass  
14 internal fundamentals exams, and one of the topics  
15 that's specifically identified is the identification  
16 of a critical state and how that critical state gets  
17 mitigated during their fundamentals training.

18 MEMBER SUNSERI: Okay, thanks.

19 MEMBER BIER: Hi, this is Vicki Bier. I  
20 had a couple of questions, one of which I think you  
21 just addressed, but my familiarity also is mainly from  
22 the commercial power reactor, so I wanted to make sure  
23 that there is a focus on how to avoid criticality and  
24 what to do about criticality, which wouldn't be a big  
25 deal for a commercial operator, but would be in your

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1 context, so I don't know if you want to comment  
2 anymore about that?

3 MR. WALLER: Sure, so we, for the training  
4 aspect of it, and there are other aspects beyond  
5 training for how it's handled, but for how we train  
6 the licensed operators on that, in the fundamentals  
7 training, as previously stated, we cover indications  
8 of criticality, reactivity effects of criticality and  
9 what we expect those effects to have on an irradiation  
10 unit.

11 We also cover the theory and operation,  
12 and then the implementation of criticality avoidance  
13 such as one over M plots. When we get into the  
14 systems training, we have a specific system that deals  
15 with criticality detection. That is covered during  
16 their systems training.

17 During their integrated operations phase  
18 training, which includes the normal, abnormal, and  
19 emergency operations, we cover the procedural steps  
20 that operators take to check for getting close to  
21 criticality and avoiding it.

22 We cover the actions to take upon receipt  
23 of a criticality alarm, and then also emergency plan  
24 training deals with actions to take upon detection of  
25 a criticality event. So, it's covered in theory, it's

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1 covered in system design, and it's covered multiple  
2 times during the operations.

3 MEMBER BIER: Great, thank you. One other  
4 question, I'm wondering whether you have a sort of  
5 chicken and egg issue with initial operation.

6 If part of licensee training, or operator  
7 training is performing evolutions in the plant, what  
8 is the level of training before you eventually operate  
9 at all and what's that transition look like to who's  
10 going to be doing those first evolutions, et cetera?

11 MR. WALLER: All right, so that's also a  
12 good question and something that we have considered  
13 for the initial class because the initial class will  
14 obviously be different than any subsequent class just  
15 because of the nature of the construction and  
16 commissioning.

17 We so have some models to follow from  
18 other recently constructed facilities and NRC  
19 licensing programs. The main thing that we're going  
20 to do for the on-the-job in the field training phase  
21 is the operators are an integral part of the  
22 commissioning and testing of the plant.

23 At the commissioning and testing of the  
24 plant, the tasks that the operators will perform line  
25 up very well with what we would identify as operators

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1 performing as part of their on-the-job training.

2 So, we intend to take credit for  
3 operations that operators perform during the  
4 commissioning phase, and that's also in line with what  
5 ANCI-15.4 states as taking credit for evolutions for  
6 training that are not part of the training program as  
7 specified.

8 We also have -- we're using, for example,  
9 on the slide that we're about to cover in the  
10 application process, using the 398(a). We do have  
11 tools in the 398 via the waiver process, so for some  
12 things, it can't be done until we reach an operating  
13 license state to have those requirements performed at  
14 that point with appropriate levels of supervision in  
15 place.

16 MEMBER BIER: Thank you.

17 MR. WALLER: Okay, so moving onto the  
18 application process, the application process for us is  
19 really no different than any other place that has an  
20 NRC licensed operator.

21 We use the NRC form 398 for the  
22 application of the candidate. We follow the research  
23 and test reactor standards when filling it out, and we  
24 also use an NRC form 396 for medical evaluations and  
25 that medical evaluation is already set up with the



1 local hospital in the area in their occupational  
2 safety health department.

3 We do an internal review of a SHINE  
4 candidate before we sent them to the NRC exam. This  
5 is a review to make sure that the medical requirements  
6 are met, that the eligibility requirements are met,  
7 and that we are confident that they would pass an NRC  
8 written exam and NRC operating exam.

9 As far as a review of the program for  
10 initial training, there's two avenues that we use to  
11 assess it. One is part of the systems approach to  
12 training.

13 There is an actual performance evaluation  
14 after training that's targeted for a specific time  
15 frame after a candidate graduates the training program  
16 for feedback incorporation and improvement of the  
17 program. It's also assessed by the review and audit  
18 committee every three years.

19 CHAIRMAN BALLINGER: This is Ron  
20 Ballinger. I have, I guess, a two-part question, not  
21 being an expert in this area at all, so I'm probably  
22 going to duplicate things, but the application form is  
23 generally for operating a nuclear facility and I'm  
24 assuming that means the accelerators here, but there's  
25 an additional part of SHINE which involves the

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1 separation and the chemistry side. Would you be  
2 modifying the application in some way to evaluate a  
3 candidate's aptitude for this kind of thing? I guess  
4 that's the question that I have.

5 MR. WALLER: Okay, so I interpret that  
6 question as you're asking about the  
7 radiopharmaceutical technicians that are performing  
8 the chemical operations for the hot cells?

9 CHAIRMAN BALLINGER: Yes, yes.

10 MR. WALLER: Okay, so those positions are  
11 currently not a licensed operator position --

12 CHAIRMAN BALLINGER: Right.

13 MR. WALLER: -- but they are under the  
14 supervision of a licensed operator, so the answer to  
15 that is two parts, the licensed operators that would  
16 be overseeing those personnel, their training program  
17 for the systems training, their integrated operations  
18 training, and anything as far as specific  
19 administrative controls. They are trained on all of  
20 those as relevant to what a radiopharmaceutical  
21 technician would do.

22 Radiopharmaceutical technicians also have  
23 a training program that's based on a systems approach  
24 to training, so they get a version of operator  
25 training. It's just not a licensed operator training

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1 program.

2 CHAIRMAN BALLINGER: Yeah, thanks. I  
3 mean, I'm sure that's absolutely correct. I'm just --  
4 there is at least the potential nexus with safety on  
5 the nuclear side, so that's why I asked the question.

6 MR. WALLER: All right, so that's how we  
7 train operators when they come in through the front  
8 door. Now let's talk about how we train an operator  
9 that has a license.

10 So, we'll start our licensed operator  
11 continuing training program within three months of  
12 receiving our first operator license, whenever that  
13 happens to be. It conforms to the requirements of 10  
14 CFR 55.59(c) and follows the guidance of ANSI-15.4-  
15 2016.

16 Basically, what all of the regulations  
17 specify is you have to have a requalification program  
18 that is continuous and no more than 24 months in  
19 length, so that's what we used.

20 We have a 24-month long biennial  
21 requalification cycle. As soon as one cycle ends, the  
22 next cycle starts up immediately. The 24-month long  
23 cycle is divided into two 12-month long annual cycles.

24 The medical certifications are done every  
25 two years in accordance with ANSI-15.4-2016. That

1 two-year period ISI is independent of the biennial.  
2 It is its own period ISI. It is tracked separately.

3 And then as part of our requalification  
4 program, we do inform the NRC per 10 CFR 50.74 of any  
5 significant changes to operator license status, for  
6 example, if a licensed operator transfers internal to  
7 SHINE and is no longer in that role, if a licensed  
8 operator leaves the company, or if a significant  
9 medical event has occurred that would change the  
10 licensed operator status.

11 MEMBER HALNON: Hey, Brent, this is Greg  
12 Halnon. Can you go back on your requal cycle and just  
13 kind of frame it up for us from the way the operating  
14 shifts look like, how many shifts, how often?

15 You know, what is their shift rotations  
16 and how do they attend requal training? Is it -- you  
17 know, can you kind of just walk us through what a --  
18 you know, is it a six-week cycle, a five-week cycle,  
19 whatever the case may be?

20 MR. WALLER: All right, so I'll handle the  
21 training piece and then I'll defer to our operations  
22 manager who is here for the actual operator shift  
23 cycles.

24 We do quarterly cycles for licensed  
25 operator continuing training, so four cycles a year,

1 eight cycles in a biennial requalification cycle. As  
2 far as the rotation, I'm going to turn it over to the  
3 ops manager, Kris Ruetz.

4 MR. RUETZ: Good morning, everyone. This  
5 is Kris Ruetz, the operations manager. So, as far as  
6 our operational shift schedule, we're going to use,  
7 follow kind of a typical DuPont type of schedule where  
8 we're going to have four crews of people that are  
9 going through rotating 12-hour shifts, day and night  
10 shifts. So, it's a four-week rotation until you start  
11 the rotation over again, so --

12 MEMBER HALNON: Okay, on the --

13 MR. RUETZ: -- does that answer the  
14 question about shift rotation?

15 MEMBER HALNON: Yeah, on the -- is there  
16 going to be like a reserve shift that's on sometimes  
17 or, I mean, or are they just one shift only?

18 MR. RUETZ: So, as of right now, we have  
19 no plans for a reserve shift. That's going to kind of  
20 depend on how our meeting looks coming out of the  
21 licensed operator training program.

22 MEMBER HALNON: Okay, that's fair. The  
23 first 12-month cycle, are you going to stagger them?  
24 Is there going to be a lucky group of people that get  
25 to do requal in 12 months or are you going to just

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1 keep them all on the same two-year cycle?

2 MR. WALLER: Okay, so we plant to, when we  
3 have the initial license class comes through, we would  
4 expect all of the licenses to come in roughly within  
5 the same period of time. We would start our  
6 requalification cycle almost as soon as we have our  
7 licensed operators and that would start our biennial  
8 requalification cycle.

9 At some point in the future, we may short  
10 cycle a continuing training cycle to get the starting  
11 in any month at a more convenient point either for us  
12 or for the NRC examiners, but at the moment right now,  
13 that's a future thing and we just intend to start the  
14 biennial requalification cycle within three months of  
15 our first license.

16 MEMBER HALNON: Yeah, that makes sense.  
17 Thank you.

18 MEMBER BIER: One other question, do you  
19 envision that people would be permanently on day or  
20 night shift or could that change over the course of a  
21 month or two?

22 MR. WALLER: No, so the schedule I  
23 mentioned previously is our current plan and that is  
24 subject to change, but the plan is for people to  
25 rotate through the day and night shifts.

1                   MEMBER SUNSERI: This is Matt. One more  
2 question maybe for the operations manager. Are you  
3 going to have the, like an active license and an  
4 inactive license arrangement where an operator has to  
5 stand so many watches to keep the license active?

6                   MR. WALLER: Yeah, so there is a  
7 proficiency requirement. When we go to the next  
8 slide, you can kind of see where we have the check.

9                   As far as the intention, I'll defer that  
10 to the operations manager, but as far as the  
11 capability goes, we do track anybody that has a  
12 license and making sure that they meet all of the  
13 requirements to maintain their license, which is  
14 medical, proficiency, manipulations that have to be  
15 performed in the plant, and up to date on training.

16                   So, the program can support it. It's  
17 whether or not ops has the staffing to have that.  
18 I'll defer to the operations manager.

19                   MR. RUETZ: Yes, so currently we have no  
20 plan for maintaining the inactive license type state  
21 that you had mentioned.

22                   MEMBER SUNSERI: Okay, all right, that's  
23 fine.

24                   MR. RUETZ: Just the maintaining of  
25 tracking of proficiency like Brent, the training

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1 manager, mentioned.

2 MEMBER SUNSERI: Yeah, yeah, no, that's  
3 good. Thanks.

4 MR. WALLER: All right, so this table kind  
5 of breaks down the, how often we're tracking various  
6 things that are part of the continuing training  
7 program. Like I said, we plan on doing licensed  
8 operator continuing training quarterly.

9 This doesn't take the place of we have the  
10 ability to do just in time training for any special  
11 evolutions that come up in the plant, but for any one  
12 cycle of training, we would cover any facility design  
13 changes, procedure changes, or license changes that  
14 are applicable to a licensed operator.

15 We'll do training lectures every quarter.  
16 We check and make sure documentation of proficiency is  
17 accomplished every quarter. We do abnormal and  
18 emergency procedure reviews once per annual cycle, and  
19 we verify that all reactivity significant control  
20 manipulations are complete once per annual cycle.

21 We administer an operating test once per  
22 annual cycle. A written exam, the NRC written exam is  
23 administered once per biennial cycle, and then the  
24 medical exam is independent of the biennial training  
25 cycle, but that occurs every two years in accordance

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1 with COC 54 2016.

2 As far as the content for the continuing  
3 training program goes, it lines up very close with the  
4 initial training program, so the applicable parts of  
5 10 CFR Part 55, any facility modifications, procedure  
6 changes, topics that are identified by the systematic  
7 approach to training, relevant industry experience,  
8 and then any identified operator weaknesses, gaps,  
9 anything observed on shift would also be covered.

10 The program is reviewed via two methods.  
11 We have the systems approach to training which has a  
12 built-in feedback mechanism and we also have an  
13 assessment by the review and audit committee every 24  
14 months. And that's the last slide for the operator  
15 training program presentation.

16 CHAIRMAN BALLINGER: Thank you.  
17 Questions, additional questions from the members or  
18 consultants? Thanks again. Can we switch over to the  
19 NRC side? There we go. Thank you.

20 MR. TATE: Good morning. Can you hear me  
21 okay?

22 CHAIRMAN BALLINGER: Very well.

23 MR. TATE: Thank you. So, good morning.  
24 My name is Travis Tate and I am the Branch Chief of  
25 the Non-Power Production and Utilization Facility

1 Oversight Branch or UNPO. UNPO is conducting the  
2 review of FSAR Chapter 12.10, SHINE operator training  
3 and requalification program.

4 I think it is important to note that there  
5 are no specific regulations for operator licensing of  
6 a facility such as SHINE. However, SHINE has provided  
7 the requalification training program as part of their  
8 application.

9 The staff is conducting a review of the  
10 program based upon specific application of the  
11 applicable portions of Part 50 of regulations to  
12 SHINE's operations. Next slide, please?

13 So, the SHINE facility is under NRC review  
14 for licensing in accordance with the applicable  
15 requirements under Part 50. In accordance with  
16 Paragraph B8 of 10 CFR 50.34, an applicant for a  
17 facility operator license is required to submit a  
18 description and plans for implementation of an  
19 operator requalification program that meets the  
20 requirements in 10 CFR 55.59.

21 The operator requalification program is  
22 intended to ensure that operators are competent to  
23 operate and safely shutdown the facility.  
24 Additionally, SHINE submitted an initial training  
25 program. However, there are no applicable regulatory

1 requirements or guidance associated with an initial  
2 training program.

3 The only regulatory requirements that  
4 exist for training and qualification of licensed  
5 personnel are contained in 10 CFR 50.120 and applies  
6 to the training and qualification of nuclear power  
7 plant personnel.

8 So, none of the requirements in 50.120  
9 apply to SHINE, which is being reviewed for licensing  
10 as a production and utilization facility. Therefore,  
11 the NRC staff will not render a sufficiency  
12 determination on the initial training program. Next  
13 slide, please?

14 So, just an overview of the government  
15 regulations for this review. They are 10 CFR 50.34  
16 which is the contents of applications and technical  
17 information, 50.54 which is conditions of licenses,  
18 and 50.59, which is requalification. Next slide,  
19 please?

20 The NRC staff evaluated the sufficiency of  
21 the SHINE requalification training program using the  
22 guidance and acceptance criteria from Section 1210 in  
23 NUREG 1537, Parts 1 and 2, and the ISG augmenting  
24 NUREG 1537, Parts 1 and 2.

25 Part 1 gives guidance to non-power reactor

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1 licensees and applicants on the format and content of  
2 applications to the NRC for licensing actions and Part  
3 2 gives guidance on the conduct of licensing action  
4 reviews to NRC staff who review non-power reactor  
5 licensing applications. Next slide, please?

6 The requalification program elements  
7 evaluated by the staff include the schedule, the  
8 preplanned lectures, on-the-job training activities,  
9 operator evaluations, and the required recordkeeping.  
10 Next slide?

11 So, the SHINE continuing training program  
12 describes how the applicant's program for operators  
13 and senior operators will meet the requalification  
14 program requirements in 55.59.

15 The NRC notes that SHINE also commits to  
16 following industry guidance in ANSI Standard 15.4, the  
17 2016 version, related to the selection and training of  
18 personnel for research reactors.

19 SHINE's two-year requalification program  
20 cycle meets the acceptance criteria for program  
21 duration contained in the NUREG and is consistent with  
22 the guidance in Section 6.2 of the ANSI standard.

23 The program must include preplanned  
24 lectures on a regular and continuing basis throughout  
25 the license period in those areas where operator and

1 senior operator written examinations and facility  
2 experience indicate that emphasis in scope and depth  
3 of coverage is needed. SHINE's preplanned lectures  
4 are based on topics related specifically to the  
5 operations of a SHINE facility.

6 The program must include on-the-job  
7 training such so that the licensed operator  
8 manipulates the plant controls and each licensed  
9 senior operator either manipulates the controls or  
10 directs the activities of individuals during plant  
11 control manipulations during the time of the  
12 operator's license. The SHINE program requires ten  
13 reactivity manipulations per annual requalification  
14 cycle.

15 The program must include on-the-job  
16 training so that each licensed operator is cognizant  
17 of facility design changes, procedure changes, and  
18 facility license changes.

19 So, SHINE's program includes document  
20 reviews that will be conducted to ensure that licensed  
21 individuals are cognizant of all design, procedure,  
22 and license changes.

23 The program also must include evaluations  
24 of the licensed operators and SHINE's program includes  
25 abnormal and emergency procedure reviews that will be

1 performed once per annual qualification cycle.

2 Specific content of training sessions is  
3 based on an observation of operator performance and  
4 items identified as weaknesses in the training program  
5 or operator knowledge as determined by operating  
6 events, examination results, and crew and individual  
7 performance gaps. Next slide, please?

8 The program includes license conditions,  
9 license condition information for licensed operators.  
10 Under the proposed program, licensed operators are to  
11 perform four hours of license duties on a quarterly  
12 basis consistent with the requirement for research and  
13 test reactors.

14 For licensed operators who have not met  
15 the proficiency requirements, will perform a minimum  
16 of six hours of license duties under the direction of  
17 a qualified individual holding the same or higher  
18 level license prior to being reinstated consistent  
19 with the requirements of research and test reactors.

20 I note that SHINE, in this area, SHINE is  
21 not considered a research reactor or a test reactor,  
22 and as such, the research and test reactor provisions  
23 of 55.53(e) and F2 are not applicable to SHINE.

24 Following the staff request for  
25 information, SHINE submitted an exemption request from

1 the requirements of 55.53(e) and F to modify the  
2 minimum number of requirements required for licensed  
3 operators to maintain active status and to restore  
4 active status. That exemption request is still,  
5 review is still ongoing.

6 The program also implements a drug and  
7 alcohol testing program for licensed operators that is  
8 consistent with the requirements of 55.53 and  
9 consistent with the guidance of Section 8 of the ANSI  
10 standard.

11 Audits for the retraining and  
12 requalification program for the operating staff are to  
13 be conducted at least once every other calendar year  
14 with the interval between audits not to exceed 30  
15 months. Next slide, please?

16 So, evaluation findings and conclusions,  
17 SHINE's licensed operator continuing training program  
18 is in accordance with the applicable regulations for  
19 requalification contained in 55.59, it meets the  
20 acceptance criteria in NUREG 1537, and is consistent  
21 with the ANSI standard.

22 The licensed operator continuing training  
23 program provides reasonable assurance that  
24 requalification for licensed operators and licensed  
25 senior operators will be carried out in a manner that

1 ensures knowledge, skills, and proficiency will be  
2 maintained and is sufficient for issuance of an  
3 operator license. Next slide, please?

4 So, operator initial training is intended  
5 to ensure that applicants will be prepared for a  
6 license under Part 55 and the facility will be  
7 operated by competent operators.

8 Again, Section 5120 of 10 CFR Part 50 does  
9 not apply. An applicant is permitted to follow the  
10 industry guidance and ANSI Standard 15.4 for selection  
11 and training of personnel. Next slide, please?

12 The training program for SHINE is  
13 described in the licensed operator initial training  
14 program. SHINE's licensed operator initial training  
15 program includes the commitment that trainees will  
16 only operate controls under direct supervision of a  
17 licensed operator, reactivity manipulation plans for  
18 licensed operator candidates, plans to account for  
19 previous experience and training, training program  
20 scope and topics for operators, the scope and topics  
21 for senior operators as well, the medical  
22 certification and fitness for duty, licensed operator  
23 candidate selection and qualifications, the evaluation  
24 of the licensed operator candidates, periodic program  
25 review and recordkeeping. Next slide?

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1 SHINE's licensed operator continued  
2 training program is consistent with the guidance  
3 contained in industry standard ANSI 15.4, and that's  
4 my last slide.

5 MEMBER HALNON: Hey, Travis, this is Greg  
6 Halnon. It looks pretty good from an operator  
7 training perspective. Have you guys thought through  
8 how the NRC staff licensing folks will be educated and  
9 trained on this so that they can ensure the operators  
10 are competent?

11 MR. TATE: Yes, we have -- you know, we  
12 are, I would say -- oops, did I -- can you still hear  
13 me?

14 MEMBER HALNON: Yeah, we're good.

15 MR. TATE: Okay, I heard a click. I  
16 thought I had muted. So, yes, we are looking at their  
17 operations and trying to understand and making sure  
18 that we understand, you know, how the facility will be  
19 operated and, you know, how we would go about putting  
20 together the examination of those operators.

21 MEMBER HALNON: Okay, there's still some  
22 time, but you're working through that, okay, thanks.

23 MR. TATE: Correct.

24 MEMBER BIER: Hi, this is Vicki Bier  
25 again, and I apologize. My questions are actually

1 follow-ups for the SHINE people, so if I could do that  
2 now. I just have more questions about the shift work.  
3 One is do you anticipate that teams will stay together  
4 and rotate through the shifts so that the same people  
5 are working together?

6 MR. RUETZ: Yes, this is Kris Ruetz, the  
7 operations manager. So, that is our intention at this  
8 time. Again, that is subject to change, but our plan  
9 is to generally keep the same shift complement, same  
10 group of people together --

11 MEMBER BIER: Okay.

12 MR. RUETZ: -- in a given shift.

13 MEMBER BIER: Yeah, and, of course, I  
14 realize, you know, that may change with absences or  
15 whatever, but that's the normal situation. Do you  
16 anticipate that -- I guess one question is I don't  
17 really have a good visualization of how busy or active  
18 a typical shift will be, and this is towards the  
19 question of is 12 hours going to be really fatiguing  
20 or is operations going to be in steady state much of  
21 the time where 12 hours is not that long?

22 MR. RUETZ: So, the amount of activities  
23 during a shift will vary based on our planned schedule  
24 such that we've kind of identified the fact that the  
25 way our operational tempo will work will give us the

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1 ability to potentially identify high activity shifts,  
2 and if it's necessary, allow us to provide additional  
3 personnel to that shift, such as if we had a Monday  
4 day shift that was particularly busy for the schedule,  
5 we could accommodate that ahead of time and plan for  
6 additional operators as necessary.

7 MEMBER BIER: Okay, so that people still  
8 get their breaks and et cetera. The one additional  
9 question I have is did you give consideration to a  
10 slower rotating schedule and was that not done because  
11 it doesn't fit the operational needs or, you know,  
12 what was the consideration in going with the DuPont  
13 schedule?

14 MR. RUETZ: So, is your question like a  
15 longer period of time before the schedule repeats and  
16 starts over or is it relating to the 12 versus eight  
17 hours or something else?

18 MEMBER BIER: No, I'm asking like if  
19 somebody is assigned to days versus nights, there are  
20 shift schedules where somebody might be on a night  
21 shift for like a whole month and then day shift for a  
22 whole month for example. It just switches less often.

23 MR. RUETZ: Yeah, I understand, so we did  
24 look at schedule alternatives, but just based on our  
25 experience here with the personnel that work at SHINE,

1 most of us do have the commercial reactor experience.  
2 We felt that the DuPont schedule would be best for our  
3 current operational tempo.

4 And again, like I said previously, it is  
5 subject to change, so if we find out that, you know,  
6 potentially another shift work schedule would be  
7 better, then we could make that change later on.

8 MEMBER BIER: Yeah, I am far from an  
9 expert on shift work, but I did look into it some  
10 many, many years ago and my understanding is that just  
11 from a physical health point of view of like sleep  
12 hygiene and things like that, that slower rotations  
13 are easier on the employees, but I'm not an expert on  
14 how to fit that into, you know, an organization's  
15 needs, et cetera, so I just wanted to raise that,  
16 okay.

17 MEMBER HALNON: Yeah, this is Greg. I  
18 just have kind of a follow-up. Actually, I lost my  
19 train of thought.

20 MEMBER BIER: Oops, maybe you didn't get  
21 enough sleep.

22 MEMBER HALNON: Yeah, I think I was going  
23 to address your questions, Vicki. The four shift  
24 rotation is pretty well established, and when we put  
25 the fatigue rule in place, there was a tremendous

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1 amount of work by Dr. Desaulniers and the NRC staff on  
2 working with the industry on the best way to do that  
3 rotation, so I'm pretty confident in the four shift.  
4 If it was a three shift rotation, I'd be a little bit  
5 more concerned, but four shift is decent.

6 The question I had was whether or not  
7 there will be a union contract. Is this a union  
8 facility or a non-union facility?

9 MR. RUETZ: It's currently a non-union  
10 facility.

11 MEMBER HALNON: Okay, so you'll have a  
12 little bit more flexibility in adjusting first of a  
13 kind technology to the human factors piece of this  
14 then.

15 MR. RUETZ: That's correct.

16 MEMBER HALNON: Okay, thank you.

17 CHAIRMAN BALLINGER: Does that complete  
18 the questions? Okay, let me -- I may be assuming  
19 facts not in evidence, but we're going pretty quick,  
20 and my question to the SHINE folks is if we have an  
21 opportunity to move some of the afternoon  
22 presentations into the morning, can that be done? The  
23 staff has already said that they're fine, but I need  
24 to be sure that the SHINE folks can do it.

25 MR. BARTELME: This is Jeff Bartelme. We

1 got considerable flexibility today. We should be able  
2 to do that. We should be able to support that.

3 CHAIRMAN BALLINGER: Good, I've probably  
4 condemned us by even asking the question, but okay.  
5 So, let's -- now we have the section on human factors,  
6 so the SHINE folks are up. I guess can we get the  
7 SHINE presentation up?

8 MR. RUETZ: Can you guys see the --

9 CHAIRMAN BALLINGER: Ah.

10 MR. RUETZ: Can everyone see the slides?

11 CHAIRMAN BALLINGER: Yes, now we can.  
12 Thank you.

13 MR. RUETZ: All right, good morning,  
14 everybody. This is Kris Ruetz, the operations manager  
15 at SHINE and I'll be talking about human factors  
16 engineering today.

17 So, just an outline of the slides I'll be  
18 covering today, so I'm going to give a brief overview  
19 of our human factors engineering, our HFE program,  
20 talk about our HFE design guidelines, our HFE design  
21 checklist, how we evaluate alarm hierarchy, some  
22 additional information on equipment labeling, and then  
23 finish off with a discussion about how we validate our  
24 operating procedures.

25 So, to begin an overview of our HFE

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1 program, so SHINE incorporates HFE principles into the  
2 design of the facility control room, the display  
3 screens, and the operator interfaces. The SHINE  
4 operations department works with the engineering  
5 department to ensure that human factors are considered  
6 throughout the design process.

7 So, SHINE evaluates HFE as part of kind of  
8 three different phases. We evaluate it as part of  
9 initial design, which I call the paper designs. So,  
10 before anything is built and implemented into the  
11 facility, we evaluate the intended design.

12 We evaluate it from actual design  
13 implementation. Once the facility is being built and  
14 equipment is installed, we confirm the as-built design  
15 to the initial design. And then we also evaluate it  
16 from the future modification aspect, so that includes  
17 both permanent and temporary modifications.

18 So, how we evaluate HFE factors, we  
19 perform a checklist that compares the design to the  
20 recommended design guidelines that we have in our HFE  
21 design guidelines that I'll cover briefly. HFE  
22 evaluations of those checklists are maintained as  
23 official records.

24 So, for our HFE design guidelines, again  
25 this is implemented through the use of that checklist

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1       that I just mentioned. The design guidelines are all  
2       recommendations. There are no requirements.

3               So, our design guidelines are kind of  
4       split into four different categories. We have  
5       instrumentation and control panel layout, main control  
6       room layout, human system interface design criteria,  
7       and alarm system criteria.

8               The design guidelines are provided to the  
9       vendors that are working on the SHINE HSIs, so they  
10      get a chance to look at them and review them, and make  
11      comments on them prior to them beginning work on the  
12      SHINE HSIs.

13              And then the design guidelines themselves  
14      are derived from the relevant industry standards, the  
15      majority of which are the NUREG-0700, the human system  
16      interface design review guidelines.

17              MEMBER HALNON: Hey, Kris, this is Greg  
18      Halnon. On this control room layout, was part of the  
19      criteria to limit the distractions to the operators?

20              MR. RUETZ: In a way, yes. The holistic  
21      view of implementing the HFE design guidelines is to  
22      ensure that operators are able to efficiently perform  
23      the duties and activities that are required of them,  
24      so that would include elimination of distractions.

25              MEMBER HALNON: In the documentation, the



1 two entry doors to the control room, every time  
2 somebody enters, it will drive the attention of the  
3 operators to the door rather than the control board  
4 because the operators are looking at the control  
5 board, but in their peripheral vision would be the two  
6 doors.

7 Is that a set design or do you have some  
8 other plans to limit the distraction every time  
9 somebody comes into a control room to take the  
10 attention of the operators away from the control  
11 board?

12 MR. RUETZ: Yeah, so the design of people,  
13 personnel entering the control room, that is a set  
14 design. Our intention is to limit normal access to  
15 and from the control room through a single door such  
16 that you're not looking back and forth between the two  
17 doors, so normal personnel access will be through a  
18 single door.

19 MEMBER HALNON: Okay, so the operators  
20 will just look to the left instead of to the right,  
21 but still, it distracts every time somebody comes in  
22 that door. The operators -- it's going to have some  
23 kind of attention distraction regardless of whether  
24 you're using two doors or just one.

25 So, I guess my point, if it's already a

1 set design, consider that because during critical  
2 evolution surveillances or other types of evolutions,  
3 you know, the industry has worked extremely hard on  
4 making sure that the distraction of the operators is  
5 limited to only what's necessary, and that most of the  
6 entry doors to the control rooms that we've seen are  
7 behind and they require permission to enter and those  
8 types of things, so consider that in your protocols  
9 for getting people into the control room.

10 MS. KOLB: So, thank you for those  
11 comments. This is Catherine Kolb. One additional  
12 thing to consider is, you know, we do have access  
13 controls on the various rooms such that we can limit  
14 the people that have the ability to enter the control  
15 room. We don't expect random staff to be wandering  
16 into the control room at any given time.

17 MEMBER HALNON: Okay, yeah, that's good  
18 and I think that's consistent with what we see in the  
19 industry. However, we don't normally see a door where  
20 the only place to come in and out of the control room  
21 is in the eyesight of the operators of the control  
22 board at the same time, so just consider that, maybe  
23 some partitions or some other type of controls to  
24 prevent the operators from being distracted.

25 MR. RUETZ: I appreciate the comments.

1 Thank you. Any other comments or questions before  
2 moving on?

3 DR. BLEY: This is Dennis Bley. In your  
4 human factors engineering program, you don't seem to  
5 do something that is done typically in power reactors  
6 and that is try to identify critical human actions  
7 which become important to think about as you design  
8 your procedures and in your safety analysis. Have you  
9 done some of that or is that done somewhere else?

10 MR. RUETZ: So, it is important to note  
11 that SHINE does not rely on the operator actions to  
12 respond to an event. So, when we discuss human  
13 critical actions, we don't have specific timed  
14 actions, whereas a nuclear power plant does have  
15 those.

16 DR. BLEY: Yeah, but some of the ones we  
17 find for a nuclear power plant don't come up unless  
18 you have an abnormal condition that requires the  
19 operator to get involved, which isn't your normal  
20 operations and in the plan, so the things that --

21 If you're in the middle of an event that  
22 leads to an accident, there are things that operators  
23 need to do, and perhaps some of those are very  
24 important, and this is where typically they get  
25 identified. I guess if I understand you right, they

1       only get identified in the safety analysis if somebody  
2       thinks of them there.

3               MS. KOLB:   Yes, this is Catherine Kolb.  
4       That is the place where we would have identified any  
5       important human actions of those kind that are  
6       required to mitigate accidents, but as discussed in  
7       our safety analysis presentation, we did not identify  
8       any human actions that were required to respond to  
9       mitigate an event, so we didn't include that in our  
10      human factors engineering program because there  
11      weren't any of those actions identified.

12             DR. BLEY:   Okay, we have a little bit of  
13      a hole here since we don't have another facility like  
14      this out there, but operating experience may teach us  
15      we missed something here. I don't know how hard we've  
16      thought about that aspect.

17             MR. RUETZ:   So, I am going to discuss in  
18      a little bit the way we do our procedure validation  
19      and that might shed some more light on what your  
20      comments and questions are.

21             DR. BLEY:   I'm sure it will help.

22             MEMBER BIER:  Hi, I have one other follow-  
23      up.   Is the checklist that's used for the human  
24      factors design, is that available to us somewhere or  
25      can that be shared or --

1 (Simultaneous speaking.)

2 MEMBER BIER: -- maybe it's been shared  
3 and I haven't found it.

4 MR. RUETZ: I don't believe we've made  
5 those available. Those are something that we can --  
6 we can make those available.

7 MEMBER BIER: That would be super. And a  
8 follow-up question, a checklist seems like a very good  
9 tool for making sure that things are not missed, but  
10 it also kind of focuses attention on the things that  
11 are on the checklist and it may be useful to have kind  
12 of an additional holistic review of just a sanity  
13 check.

14 You know, what strengths and weaknesses do  
15 we see in this design separate from the checklist and  
16 can you talk about whether that kind of more holistic  
17 review has taken place?

18 MR. RUETZ: Yeah, I think what you might  
19 be referring to again might be covered when I talk  
20 about procedure validation, just I guess I can kind of  
21 hint at it now, but essentially for procedure  
22 validation, we're going to take our procedures that  
23 we've written and do an actual walkthrough in the  
24 facility hand over hand to ensure the procedure can be  
25 performed as written, so I think that would alleviate

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1 some of the issues that you might be referring to.

2 MEMBER BIER: Yeah, that's part of it, but  
3 also I think even before construction of the  
4 equipment, it just, you know, an additional  
5 walkthrough of, you know, is everybody comfortable  
6 with this design, you know, maybe getting an outside  
7 expert to review it who wasn't involved in the design  
8 process or whatever.

9 Because I know for the commercial power  
10 plants, you know, we had an experience where a lot of  
11 control rooms had major redesigns after they were  
12 implemented, and obviously some of that is now in  
13 lessons learned that anybody would know about before  
14 doing their design, but it's a lot easier to change  
15 designs before they're in hardware.

16 MR. RUETZ: I understand your comment and  
17 I think one thing that kind of helps us out in that  
18 aspect is the fact that the operations department is  
19 incredibly involved in the whole human factors  
20 engineering process and HSI design such that we work  
21 with the vendors that are developing the HSI software  
22 and interfaces on a nearly daily basis just as  
23 operators, so we are the end users of it, so it's  
24 extremely helpful for us to be involved in essentially  
25 the design process of those.

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1 MEMBER BIER: Okay, thank you.

2 MR. RUETZ: All right, so moving on, more  
3 discussion on the human factors engineering design  
4 checklist. So, those checklists are used to compare  
5 the design to the recommended design guidelines.

6 The checklists are filled out by the  
7 operations department and are used, again, during  
8 those three phases I discussed, during initial design,  
9 after installation, and as part of equipment  
10 modifications, and again, the checklists are kept as  
11 records.

12 Any issues that are identified during  
13 performance of the checklists are tracked via the  
14 SHINE issues management process which is our  
15 corrective actions program.

16 All right, so next I'll cover alarm  
17 hierarchy. So, most of our facility alarms will be  
18 received in the control room via the process  
19 integrated control system, the PICS. PICS displays  
20 alarms on a consolidated alarm page on the control  
21 room HSIs.

22 We also have stack lights in the control  
23 room that alert operators to current facility alarm  
24 status. These stack lights provide operators with  
25 high level facility alarm status, and they're broken

1 out such that each irradiation unit has its own alarm  
2 light and then there's additional alarm light for  
3 common alarms that aren't specific to an individual  
4 irradiation unit.

5 So, we have four different categories of  
6 alarms. We have high, which is a red light and  
7 audible alarm, medium, a yellow light, and low, a blue  
8 light, and then informational alarms, which there's no  
9 stack light indication for, only a PICS alarm display.

10 MEMBER HALNON: Before you go on, could  
11 you go back and just give us a sense of what a high  
12 alarm would be?

13 MR. RUETZ: Yeah, so high alarms would be  
14 generally things that related to safety-related  
15 equipment or parameters that might lead operators into  
16 tech spec space, LCO entries, things like that.

17 MEMBER HALNON: Okay, largely operator  
18 reaction required to address the alarm?

19 MR. RUETZ: That's correct.

20 MEMBER HALNON: Okay, and that gets back  
21 to Dennis's earlier question that even though no  
22 license basis event requires operator action, there's  
23 a tremendous amount of important operations that do  
24 require operator response. Just a comment, thanks.

25 MR. RUETZ: Thank you. For equipment



1 labeling, equipment and pipe labels are included  
2 within the scope of the HFE program. Equipment labels  
3 include a descriptive name and equipment designator,  
4 which is our unique equipment identifier.

5 Equipment labeling includes components  
6 such as valves, pumps, and tanks. Pipe labels include  
7 the system name and the arrow showing direction of  
8 flow.

9 During facility construction and  
10 commissioning process, equipment and pipe label  
11 verification is performed as part of turning over  
12 systems to operations and here I have some pictures of  
13 example labels.

14 And finally, I'll just talk about  
15 operating procedure validation. So, operating  
16 procedures, including abnormal and emergency  
17 procedures, are validated prior to being issued for  
18 use.

19 The process for procedure validation  
20 varies based on the type and the content of the  
21 procedure. However, most validations will consist of  
22 a step by step facility walkthrough of a procedure  
23 after the related equipment has been installed.

24 So, alternate methods may be used for a  
25 procedure validation on a case by case basis. An

1 example would be a tabletop discussion which might be  
2 more, might be easier to perform for something like an  
3 emergency procedure that kind of has several branching  
4 steps in it, but the majority of validations will be  
5 the walkthrough of the facility.

6 So, the point of the procedure validation  
7 is to ensure that the operators can physically perform  
8 the procedures and provides a diverse method of  
9 checking for necessary equipment labels, kind of a  
10 last stop to make sure that we have all of our labels  
11 in place.

12 So, that's all I have for the presentation  
13 portion. Any questions or comments from anybody?

14 CHAIRMAN BALLINGER: Hearing none, thank  
15 you very much. Can we get the NRC folks up?

16 MR. SEYMOUR: This is Jesse Seymour from  
17 the human factors and operator licensing branch.  
18 Michael, could we go ahead and just get my first slide  
19 up there?

20 CHAIRMAN BALLINGER: Got it. Thank you.

21 MR. SEYMOUR: Thanks a lot. I appreciate  
22 it. My name is Jesse Seymour, and I'm a human factors  
23 technical reviewer in NRR's Operator Licensing and  
24 Human Factors Branch. I was the primary reviewer for  
25 the human factors engineering portion of the SHINE

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operating license application.

I will be providing an overview of the regulatory basis for the review. The guidance and criteria I used for it are audit activities, a basis for how we scope and graded our review approach, our technical evaluation, and, lastly, our conclusions and findings.

Next slide, please?

Okay. So, in general, we conduct human factors engineering reviews of operating license applications in order to verify that applicants are incorporating practices and applying guidelines that are acceptable. It's important to note that the SHINE FSAR follows the format used by non-power reactor facilities, such as research and test reactors. That format does not include a dedicated human factors engineering chapter as would be the case with a power reactor facility.

As a result, the areas covered by the HFE area review span various portions of Chapters 3, 7, 12, and 13, and focus on whether the HFE-related design and programmatic aspects of the application are sufficient.

Next slide, please?

The specific regulatory basis associated

1 with the SHINE application was key to the discussion  
2 of the HFE area review approach that was used. Here  
3 we have a description of the regulations that serve as  
4 the basis for the review. These regulations come into  
5 play whether we are talking about irradiation facility  
6 or the radioisotope production facility portions of  
7 the SHINE facility.

8 Design Criteria 6 addresses the SHINE  
9 control room and certain actions that it is required  
10 to be able to support. Later in the presentation we  
11 will discuss what the staff review identified  
12 concerning the nature and scope of those actions.

13 Importantly, it must be recognized that no  
14 HFE programmatic requirement exists for SHINE due to  
15 their specific regulatory basis.

16 Next slide, please?

17 Now I will discuss the guidelines and  
18 associated acceptance criteria that we used for the  
19 HFE area review of the SHINE application. As noted  
20 throughout the meeting so far, NUREG-1537 and its  
21 associated interim staff guidance served as the  
22 overall review plan for the SHINE application.  
23 Consistent with how I noted that the SHINE regulatory  
24 basis does not mandate an HFE program, NUREG-1537 does  
25 not contain any specific review criteria for human

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1 factors engineering.

2           However, NUREG-1537's Chapter 7 for  
3 instrumentation and control, more specifically  
4 Section 7.6, which addresses the control console and  
5 display instruments, does contain certain criteria  
6 that have HFE-related implications. These criteria  
7 include those for the observability of outputs and  
8 display devices, the accessibility and  
9 understandability of important controls and displays,  
10 and for control console, enunciators, and alarms.

11           Since these criteria are written in terms  
12 of a non-power reactor facility, we adapted them, as  
13 appropriate, using the guidance of the NUREG-1537  
14 interim staff guidance as interpreted according to  
15 SHINE-specific systems.

16           Next slide, please?

17           While SHINE is not a Part 70 facility  
18 applicant, the application still contains certain  
19 features that have similarities to those types of  
20 facilities. Centrally, SHINE conducted a safety  
21 analysis that identifies administrative controls that  
22 are used to reduce the likelihood and consequences of  
23 events in order to achieve acceptable levels of risk,  
24 as well as certain programmatic measures that serve to  
25 support the reliability of those administrative

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1 controls.

2 On account of this, we used guidance from  
3 both the NUREG-1537 interim staff guidance and also  
4 from NUREG-1520, which is referenced by the NUREG-1537  
5 ISG, to consider these specific areas. We noted that  
6 these administrative controls consisted of a variety  
7 of procedurally directed and prohibited actions that  
8 occurred throughout the facility, and that, in  
9 general, those controls were supported by programmatic  
10 measures in the areas of training and procedures.

11 Based upon that, we focused the HFE area  
12 review on that particular aspect of the SHINE  
13 application on procedure management, verification and  
14 validation, as well as on the training and  
15 qualification of the relevant facility personnel.

16 Next slide, please?

17 MEMBER HALNON: Jesse, it's Greg Halnon.  
18 Given all of the review criteria that you just went  
19 through, did you identify lessons learned that might  
20 make the next review more I guess efficient relative  
21 to finding the right guidance to review against?

22 MR. SEYMOUR: That's a great point. And  
23 in my Part 53 discussions that I've had with the --  
24 with the committee, we've been talking about how we're  
25 developing guidance going forward for scalable human

1 factors engineering reviews.

2 And one of the things that we've done is  
3 try to take lessons learned from this review, where  
4 we've had to, you know, really help pull apart what  
5 the facility is and figure out what the relevant  
6 guidance should be, and to apply that to that scalable  
7 HFE guidance development going forward.

8 MEMBER HALNON: Okay. That makes sense.  
9 So in the future something under Part 50 such as this,  
10 which is sort of a one off, you can refer to the new  
11 guidance that you're doing.

12 MR. SEYMOUR: That's correct. Yeah.  
13 We're trying to -- you know, we're trying to take  
14 those lessons and use them to build a better product  
15 that we can use down the road.

16 MEMBER HALNON: Okay. Thanks.

17 MR. SEYMOUR: Okay. Let's see, Slide 6?  
18 7?

19 Okay. So in order to scope and grade the  
20 human factors engineering area review and to clarify  
21 areas in which we have questions, we conducted an  
22 audit. A central focus of this audit was to better  
23 understand the specific role that SHINE facility  
24 operators will play in facility safety as this was in  
25 turn necessary for identifying what would be needed to

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1 meet Design Criteria Number 6.

2 The overall audit included the areas of  
3 the limited human factors engineering program that  
4 SHINE elected to implement, the design of the facility  
5 control room, the role of SHINE operators in  
6 maintaining both facility safety and in providing for  
7 defense-in-depth, administrative controls, operations  
8 staffing, and portions of the operator training  
9 programs.

10 The documents that we reviewed in the  
11 course of this audit included, among others, the SHINE  
12 safety analysis summary report, the SHINE human  
13 factors engineering program, the SHINE human factors  
14 engineering style guide, and the SHINE human factors  
15 engineering design checklist.

16 Additionally, we also looked at SHINE's  
17 operations procedure development program and portions  
18 of the licensed operator initial and continuing  
19 training programs. This audit report has been issued  
20 and is available. However, I should note that a  
21 portion of the audit that covers some of these  
22 materials is proprietary in nature.

23 Next slide, please?

24 From the audit we gained certain insights  
25 that served to inform our approach and acted as a



1 means of scoping and grading our review of the  
2 application. These insights included that operators  
3 are not credited to take mitigative actions in  
4 response to facility events.

5 We did note the operators who were  
6 identified as providing manual actuations of safety-  
7 related TRPS and ESFAS systems for the purposes of  
8 defense-in-depth. It should be noted, though, that  
9 this is the sting from the operator's being credited  
10 to do so.

11 They also noted that operators were  
12 credited with the implementation of administrative  
13 controls that are taken prior to the occurrence of  
14 events. Operator actions were noted to not be  
15 credited in response to events assigned from the need  
16 to evacuate the facility control room within a  
17 specific timeframe under certain circumstances.

18 Additionally, we identified through our  
19 audit that SHINE had incorporated a human factors  
20 engineering program of a limited nature. This program  
21 consists of a human factors engineering programmatic  
22 document, a style guide that is based in part on the  
23 human system interface design guidelines of  
24 NUREG-0700, and a human factors engineering checklist  
25 that is used both during the human system interface

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1 design and installation phases.

2 Next slide, please?

3 Okay. So before we get into the details  
4 of the technical evaluation, this graphic serves to  
5 summarize the material that has been covered thus far  
6 and to illustrate once more how the review, scope, and  
7 focus was arrived at.

8 SHINE is applying under Part 50 but is not  
9 a power reactor. Because of this, there is no  
10 regulatory requirement for applying the state of the  
11 art in human factors engineering to the control room  
12 design. Similarly, the NUREG-1537 review plan does  
13 not have any specific human factors engineering  
14 criteria.

15 However, that being said, Design  
16 Criteria 6 does address the need to have a control  
17 room from where actions can be taken to operate the  
18 facility safely and to perform any required acts and  
19 actions. And NUREG-1537 has certain I&C criteria for  
20 the control room that have related human factors  
21 engineering aspects.

22 By way of our audit, we noted that the  
23 accident response doesn't rely on operators taking  
24 actions, and that the operator role under such  
25 circumstances is to essentially serve as an added

1 layer of defense-in-depth and to evacuate the control  
2 room if necessary.

3 We also noted that SHINE applies a limited  
4 human factors engineering program to their control  
5 room. And that while not mandated by regulation, this  
6 program applies guidelines that are derived from, in  
7 part, NUREG-0700, and that the application of such  
8 guidelines as these generally supports those  
9 NUREG-1537 control console and display criteria that  
10 have human factors -- human factors engineering  
11 implications.

12 Finally, we also noted that SHINE credits  
13 operators' implementation of administrative controls  
14 and that these administrative controls are, in turn,  
15 supported by specific programs. So taken together,  
16 this information established the focus and scope of  
17 our HFE review.

18 Next slide, please?

19 As noted earlier, the NUREG-1537  
20 Section 7.6 criteria selected for the review were  
21 adapted for use within the context of the SHINE  
22 application using the guidance of the NUREG-1537  
23 interim staff guidance, as interpreted, based on  
24 SHINE-specific systems.

25 Under the first of these criteria, we

1 evaluated whether displays showing parameters related  
2 to facility safety would be readily observable by the  
3 operator while positioned at SHINE's facility control  
4 room operator workstations and the main control board.

5 In conducting this evaluation, we focused  
6 on the PICS and NDAS workstations used by the  
7 operators as well as on the main control board  
8 locations TRPS and ESFAS relative indications are  
9 provided. This included considerations of factors  
10 such as accessibility and visibility.

11 We noted that the control room displays  
12 and operator interfaces incorporate human factors  
13 engineering principles and that the associated human  
14 factors engineering guidelines used by SHINE included  
15 those associated with the readability, content, and  
16 arrangement of displays.

17 We found that this criteria is satisfied  
18 because outputs and displays showing parameters  
19 related to SHINE facility systems that are related to  
20 safety are readily observable by the operator while  
21 positioned at both the SHINE facility control room  
22 PICS and NDAS workstations as well as at the main  
23 control board, TRPS and ESFAS manual actuation  
24 controls, and that this is in turn supported by  
25 SHINE's HFE program.

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1                   Next slide, please?

2                   Next, we evaluated whether controls and  
3 displays of other important parameters, such as for  
4 reactivity, would be readily accessible and  
5 understandable to the operator. In conducting this  
6 evaluation, we divided the associated displays and  
7 controls up into two groups for consideration.

8                   The first group was more general in nature  
9 and focused on displays and controls other than those  
10 associated with the manual actuation of the  
11 safety-related protection systems. This included the  
12 operator workstations and their associated PICS and  
13 NDAS interfaces, the super workstation, and the  
14 features of the main control board.

15                  The manner in which radiation monitoring  
16 information is conveyed to the operators was also  
17 considered. The digital interfaces used at the  
18 workstations and the main control board were noted to  
19 incorporate human factors engineering principles  
20 within their designs.

21                  The second group focused on the specific  
22 displays and controls associated with the manual  
23 actuation of the TRPS and ESFAS systems, since these  
24 are integral to the ability of the operator to  
25 implement manual protective actions as a means of

1 providing defense-in-depth.

2 This evaluation included both the manual  
3 controls on the main control board that are used to  
4 actuate the systems, as well as the displays that  
5 would provide information to the operators to cue them  
6 that such actions are warranted.

7 We found that the human system interface  
8 will be capable of supporting the manual actuation of  
9 protective actions because displays and controls will  
10 be available in the SHINE facility control room for  
11 the manual system level actuation of safety functions  
12 and for monitoring those parameters that support them.

13 Overall, we found that this criterion is  
14 satisfied because the facility control room controls  
15 and displays are both readily accessible and  
16 understandable to the operator.

17 Next slide, please?

18 The third criteria of NUREG-1537  
19 Section 7.6 that we evaluated was whether enunciators  
20 and alarms on the control console clearly show the  
21 status of systems, such as those associated with TRPS,  
22 ESFAS, and radiation monitoring. We noted that alarms  
23 are integrated into the PICS displays, that alarm-like  
24 and audible sounds are also provided for irradiation  
25 unit and non-irradiation unit-related alarms, and that

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1 human factors engineering principles are applied to  
2 the design of the alarm systems.

3 Additionally, we noted that further alarm  
4 systems were also provided to alert operators to both  
5 criticality accident and fire conditions. We found  
6 that this criteria is satisfied because enunciators  
7 and alarms on the control console clearly show the  
8 status of systems such as operating systems,  
9 interlocks, TRPS and ESFAS initiation, radiation  
10 fields, and concentration and confinement, and that  
11 this is further supported by SHINE's human factors  
12 engineering program.

13 Next slide, please?

14 MEMBER BROWN: This is Charlie Brown.  
15 Could you backtrack a slide?

16 MR. SEYMOUR: Sure.

17 MEMBER BROWN: Okay. You talk about  
18 evaluating displays. Are these the specific displays  
19 that they are going to be using on their panels? Have  
20 they provided those to you all, or is this just what  
21 the -- what you all would typically look at?

22 MR. SEYMOUR: So what we've -- what we've  
23 looked at at this stage consists of the description of  
24 those displays that's provided in the FSAR and via  
25 audit. We have also looked at the guidelines that we

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1       apply to those displays.

2                   And an example of that that I will give  
3       you is that SHINE's human factors engineering design  
4       guidelines include guidelines that are related to the  
5       observability, content, readability, and arrangement  
6       of those displays.

7                   So what we have seen via audit is that  
8       SHINE intends to apply those guidelines during the  
9       design and during the installation phase of those  
10      displays, and then to subsequently track any  
11      discrepancies that are identified.

12                  MEMBER BROWN: Are they specific as to the  
13      type of displays? Like are they touchscreens? Are  
14      they screens that require pushbuttons or switch  
15      manipulation in order to call up various screens or  
16      functions on a screen?

17                  MR. SEYMOUR: So all displays at the  
18      workstations and the main control board are described  
19      as being digital displays. In terms of if any are  
20      touchscreens, I would have to -- I would have to defer  
21      that question back to SHINE in order to clarify that.

22                  My understanding is that the control  
23      interfaces are not touchscreen in nature. However, I  
24      would -- I would have to defer that question back to  
25      them in the event that there has been any changes to

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1 their intention.

2 MR. RUETZ: Yeah. This is Kris Ruetz,  
3 Operations Manager at SHINE. So Jesse is correct. In  
4 the control room, at least for the PICS interface  
5 there is no touchscreen capability. It's keyboard and  
6 house interface. However, I do want to point out with  
7 the remote PICS stations we do have touchscreen  
8 capability, the ones that are outside of the control  
9 room.

10 MEMBER BROWN: Okay. I was looking at the  
11 -- I didn't pull up -- where is my stupid drawing?  
12 When you talk about the remote, I was thinking that  
13 there's a facility control room where you have your  
14 basic controls. There's a production facility space  
15 also. Is that in the facility control room?

16 MR. SEYMOUR: So is that question directed  
17 at me or at SHINE?

18 MEMBER BROWN: At SHINE I guess, now that  
19 they're on.

20 MR. RUETZ: Yeah. Sorry. Could you  
21 repeat that question again?

22 MEMBER BROWN: Yeah. I was looking at my  
23 overall I&C architecture diagram that you gave when we  
24 were talking yesterday. And there -- it shows that  
25 you have what's called a facility control room human

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1 interface -- human system interface, and then another  
2 box which talked about a production facility  
3 interface. Are they separate locations, or are they  
4 all in the same space?

5 MS. KOLB: So this is Catherine Kolb. The  
6 control room includes interfaces and displays for the  
7 entire facility. So that is the irradiation units and  
8 for instruments that provide indication of processes  
9 in the radioisotope production facility as well.

10 What Kris is talking about as having  
11 touchscreens -- so in addition to the main control  
12 room where the operator sits and we can see on their  
13 trays in front of them, you know, indications  
14 throughout the facilities, there are also some local  
15 control stations for specific processes.

16 So, for example, there is -- for the  
17 tritium purification system, in the tritium  
18 purification room there is a limited function display  
19 screen with limited control specific to that system  
20 located in that room and not in the control room.

21 All of the PICS displays are a networked  
22 system, so the control room operators can see  
23 information from all of the processes that are  
24 connected in the facility, but the local displays are  
25 -- the control is limited for those local displays,

1 the touchscreens.

2 MEMBER BROWN: Are the local displays used  
3 for the normal operations, or is that just for some  
4 specific things while the main control is under the  
5 main control room?

6 MR. RUETZ: Yeah. So there won't be  
7 specific evolutions and procedures. The normal  
8 station will be the local stations, like Catherine had  
9 mentioned in the tritium purification system room.

10 However, there is -- there is nothing that  
11 is able to be performed at those local stations that  
12 cannot also be performed in the main control room as  
13 we're --

14 MEMBER BROWN: Okay.

15 MR. RUETZ: -- doing that.

16 MEMBER BROWN: So those would be --  
17 typically, you would be looking at the main control  
18 room operator controlling all of the processes.  
19 That's what I understood basically from yesterday's  
20 discussion.

21 MR. RUETZ: That is correct.

22 MEMBER BROWN: Okay. Is there an  
23 emergency control screen of any kind, an emergency  
24 screen?

25 MR. RUETZ: Can you describe what you mean

1 by "emergency screen"?

2 MEMBER BROWN: Something that says, "Hold  
3 it. I've got a big problem going on." Something --  
4 that there's a failure, irradiation alarm failure. Is  
5 there something that coordinates or evaluates the  
6 specific problems you might have to face such that you  
7 don't have to start dealing with multiple process  
8 screens when something goes on.

9 I don't know whether I'm asking the  
10 question right or not. This -- you all have -- the  
11 last time I counted the process integrated control  
12 system and counted the number of different systems  
13 you've got, there's a lot. So, which is  
14 understandable based on what you're doing.

15 So when I looked at that, it's difficult  
16 to control some problems if you -- that you may be  
17 evaluating, you've analyzed for, if you have to be  
18 cognizant of, you know, three, four, five, six  
19 different screens in the main control room.

20 That may be the wrong question. I have no  
21 idea how that applies to the overall processes. But  
22 you have a lot of different process stations from the  
23 IUs into the process -- the tritium processes, the  
24 purge systems, et cetera. So that's why I asked the  
25 question, is there an emergency control screen based

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1 on certain analyzed accidents or other type things  
2 where you may have to have consolidated information to  
3 do an evaluation as opposed to having multiple -- or  
4 trying to get to multiple screens while you're dealing  
5 with it.

6 MR. RUETZ: Yes. So I can provide some  
7 clarification on that I think. So the operator  
8 workstations that are in the control room, there are  
9 two operator workstations and one supervisor station.  
10 So three stations in total that are part of that PICS  
11 network that we mentioned.

12 Each of those stations has three screens  
13 on it. One of those three screens is designated  
14 specifically as an alarm response screen, such that  
15 that screen cannot be used for manipulating components  
16 and equipment in the facility. And if an alarm comes  
17 in, then that -- that screen will be designated to  
18 show the alarm page.

19 So it -- the alarm page and currently  
20 activated alarms will always be available to the  
21 operator who is performing equipment manipulations at  
22 the operator stations.

23 MEMBER BROWN: So that is continuously --  
24 that was continuously open, the alarm screen.

25 MR. RUETZ: The alarm screen is not

1 continuously open. However, it -- it automatically  
2 goes to the alarm screen if an alarm comes in, such  
3 that you can't perform a process using the PICS on  
4 that screen. You have to use one of the other  
5 monitors to start an automated sequence, for instance.

6 Then, if an alarm comes in, that third  
7 screen, which can be used for just monitoring purposes  
8 only, will automatically populate with the alarm page  
9 to bring that to the attention of the operators.

10 MEMBER BROWN: Okay. Let me -- let me  
11 track back to the screen popping up. You've got, I  
12 understand, three screens like you say. So if an  
13 operator is controlling something and he is utilizing  
14 one of the screens, would that screen all of a sudden  
15 start populating with alarms and the rest of it  
16 disappear and he'd have to shift screens in order to  
17 complete his operations? Or has that even been  
18 considered?

19 MR. RUETZ: No. No. So the screens that  
20 are used for equipment manipulation are the other two  
21 screens, so not the alarm designated screen.

22 MEMBER BROWN: Okay.

23 MR. RUETZ: So the alarm designated screen  
24 is -- can only be used for monitoring purposes and  
25 then it will automatically switch to the alarm page if

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1 an alarm comes in.

2 MEMBER BROWN: Okay. But the -- but the  
3 process information -- temperatures, pressures,  
4 whatever you need, nuclear indications, what have you  
5 -- they would not be blanked out if this thing starts  
6 -- you know, it's a monitoring screen. They would not  
7 be blanked out, and you'd have to look at something  
8 else, or would they be on some other screen already  
9 anyway?

10 MR. RUETZ: They would be on the other  
11 screen already anyway. The way that the screens will  
12 be set up is that they sort of drill down to lower  
13 level systems and components as you click through  
14 them, such that when you get to the screen that allows  
15 you to start a process or manipulate equipment you  
16 have the relevant information needed, the process  
17 parameters that you are talking about.

18 MEMBER BROWN: Okay. And the other  
19 question I wanted to ask -- several, rather -- are the  
20 -- take an operation you're starting up. What -- you  
21 know, you're going to start up the entire process for  
22 getting your moly-99. Do you -- how many screens do  
23 you have to access while you're doing a startup and  
24 going through the entire operation? Do you -- is that  
25 for normal ops startup, shutdown? Do you have to

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1 switch screens in order to do that? Or can you  
2 accomplish -- can the operator accomplish that from  
3 one screen?

4 MR. RUETZ: So the operators will be able  
5 to see all of the necessary information to perform a  
6 startup from a single operator station. So between  
7 the three screens --

8 MEMBER BROWN: Okay.

9 MR. RUETZ: -- they are able to see  
10 everything they need to to essentially operate the  
11 facility.

12 MEMBER BROWN: But if the alarm screen  
13 came up, they wouldn't lose something. Is that --  
14 that's what I was trying to get at. If they're doing  
15 the startup, they're using all three screens, and now  
16 these alarms come in, if they were using that screen,  
17 do they lose something and have to look somewhere  
18 else? That's -- it's a matter of taking your  
19 attention off of one thing and looking at something  
20 else.

21 MR. RUETZ: Yeah. I see your point and  
22 your comment. So the three screens that are available  
23 for the operators, they can switch between them, you  
24 know, at will and as necessary for the procedure  
25 that's being performed. So, you know, they may be --



1 to your point, they may be using that third monitor  
2 that's designated for alarm response to monitor  
3 components and equipment, and then that may  
4 temporarily switch to the alarm screen.

5 However, the operator can navigate back to  
6 that -- those indications as needed or switch one of  
7 the other two screens to those indications as needed.

8 MS. KOLB: This is Catherine Kolb.  
9 Perhaps it would help if -- so some of the times  
10 involved are proprietary, but in general starting up  
11 the facility isn't, you know, a five-minute evolution.  
12 It is --

13 MEMBER BROWN: I got that.

14 MS. KOLB: -- step-wise in accordance --  
15 in accordance with procedures, such that the, you  
16 know, the step that the operator is on, they could set  
17 up the screens that they are using to show all of the  
18 parameters required for that step.

19 And then when a new step comes, you know,  
20 maybe the difference between billing the TSD versus,  
21 you know, starting the transfer for moly production,  
22 that is -- that is separated in time significantly,  
23 such that there would be ample time to set up your new  
24 set of screens, so that you could see all of the  
25 parameters you needed for that next evolution.

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1                   So that, you know, being able to see  
2 everything all at once isn't really necessary.

3                   MEMBER BROWN: I'm sorry to beat this  
4 thing to death, but because of the number of systems  
5 you have -- I guess I faced this in the naval program  
6 as well when we were developing it -- our main control  
7 stations.

8                   One of the things we worried about -- and  
9 I guess one of the things that fell out of the old TMI  
10 evaluation -- that so many alarms were going off in  
11 many cases that operators got distracted from what was  
12 a critical alarm and what was just a nuisance alarm,  
13 like an elevator failed or a door didn't open or  
14 something like that.

15                  And I'm not saying you're going to have  
16 those types of alarms on these screens. That's not  
17 the point. It was just the nature of the operations.  
18 It's a complex operation you all are dealing with, and  
19 that's why I was -- I was asking these questions  
20 relative to that, relative to getting the operators  
21 distracted, from seeing something that all of a sudden  
22 became a critical problem.

23                  So we don't need to go into proprietary  
24 stuff. That's just all I was trying to get a feel  
25 for. Let me --

1 MS. KOLB: So I think we had -- we  
2 attempted to address some of those concerns with the  
3 alarm prioritization, such that it will be clear which  
4 alarms require, you know, immediate attention.

5 And not to mitigate things, but, you know,  
6 the operator -- you know, the procedures would say to,  
7 you know, verify that the safety actuation -- that all  
8 of the components did arrive at their safe state, you  
9 know, for confirming that things reacted appropriately  
10 per the design.

11 And so those would have higher priority if  
12 there was an actual issue in the plant versus the  
13 yellow or the blue alarms and the ones that don't  
14 cause the stack lights to illuminate, such that the  
15 people will be trained on which -- which alarms are  
16 more important than others.

17 MEMBER BROWN: Okay. The other thing you  
18 said -- and I'm referring back to Section 7.1 as a  
19 matter of fact of the FSAR -- you mentioned multiple  
20 digital display space as well as what I call display  
21 screens. Are those discrete meter -- I don't know if  
22 -- meter style? Or are they just seven segment LEDs  
23 that spin up and down as something changes rapidly?

24 MR. RUETZ: So typically speaking, I think  
25 everything you're referring to on Figure 7.1, those

1 are just, you know, typical computer monitors that  
2 relay the information to the operators.

3 MEMBER BROWN: But let me find the thing  
4 I'm -- make sure I said this correctly to you. If I  
5 can get the right paragraph here.

6 MS. KOLB: We refer to the computer  
7 monitors that are in the front of the room as static  
8 display screens, but those are just a series of  
9 computer monitors. To distinguish them from the ones  
10 that are at the desk where the people are sitting, I  
11 think those are -- you know, could be control display  
12 screens. They are -- they are both just digital  
13 displays.

14 MEMBER BROWN: Okay. I mean, a typical  
15 example, like you've got to take your temperature.  
16 It's a digital display. You've got -- numbers come  
17 up. That's what you're talking about relative to a  
18 digital display.

19 MS. KOLB: Correct.

20 MEMBER BROWN: Okay. It's not like a  
21 meter in the old days, an analog meter that had a  
22 needle and it went from -- you know, from the lower  
23 left to -- around to the lower right.

24 MS. KOLB: No. We don't have any of those  
25 incorporated into the PICS.

1                   MEMBER BROWN: Okay. That's fine. Now,  
2                   would a single screen have more than one of these  
3                   digital displays? I take it they are not discrete?  
4                   These are digital displays of data that would be  
5                   reflected on a single screen, not separate little  
6                   digital displays themselves?

7                   MS. KOLB: Correct.

8                   MEMBER BROWN: Okay. All right. I might  
9                   be almost finished and you'll be as happy as I am.

10                  DR. BLEY: Charlie, can I --

11                  MEMBER BROWN: Yeah.

12                  DR. BLEY: -- jump in with something? I  
13                  think what Charlie is getting at is on a needle  
14                  display you can see what the reading is as it changes  
15                  on a set of numbers, kind of digital display. They  
16                  are spinning fast, and you might not be able to tell  
17                  where they are. But people have implemented something  
18                  akin to a meter in software, so you can follow the  
19                  trend.

20                  I think he is asking if you can see what  
21                  an instrument reads if it's moving quickly.

22                  MEMBER BROWN: Yeah. Let me -- thank you,  
23                  Dennis. I didn't phrase it that way, so I'll be  
24                  specific. In 1978, when we started developing these  
25                  systems for the naval nuclear control stations

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1 program, all the meters you used out with the  
2 operators were KX241 meter -- you know, analog meters.

3 When we started doing everything, all the  
4 vendors we went to, they were -- they loved designing  
5 displays. I mean, and everybody that came up wanted  
6 to design displays for their equipment that they got  
7 a contract for.

8 I ended up canceling contracts on five  
9 different -- portions of five different contracts  
10 because it would have been too expensive to live with  
11 so many multiple types of displays and how they work.  
12 So we stopped it and developed a standard digital  
13 meter that looked exactly like a KX241 meter, an old  
14 analog meter. It had flying dots around the outside  
15 and a large seven-segment readout in the middle.

16 So for the fast displays, you had  
17 something moving -- you know, either going up the  
18 meter or down the meter, so you could tell even if you  
19 couldn't read the specific value of the parameter that  
20 you were -- you were interested in.

21 Now I'm not saying you need something like  
22 that. I think what -- I mean, you could -- you could  
23 duplicate something like that on a -- on a screen, on  
24 a flight screen if you want to. That can be done.  
25 I'm just -- I was asking it in that context, and I

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1 think Dennis knows I use more words than I normally  
2 need to get to the point. So that helped me out.

3 That's what I was asking about, what these  
4 types of digital displays are.

5 MR. RUETZ: Yeah. So I can appreciate  
6 your common background. I was a former reactor  
7 operator on a submarine as well. So I know exactly  
8 what standard digital meters you're talking about. So  
9 as far as -- as far as that goes, any parameter that  
10 is displayed on the PICS board for the operators can  
11 be clicked on. And if you click on it, it will have  
12 a type of bar graph histogram of the, you know,  
13 direction and trend that that parameter is going on.

14 MEMBER BROWN: Okay. All right. That's  
15 good. That answers my -- that's good enough.

16 The next question I did have was -- if I  
17 can count my paragraphs here -- they are -- in this  
18 early section also, it talked about the supervisor  
19 workstation is located at the rear of the facility  
20 control room and acts as an extension of the operator  
21 workstations.

22 The workstation is equipped with equipment  
23 display screens that allow the supervisor to monitor  
24 system status but not control facility components. So  
25 that -- so does the supervisor not have backup

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1 capability? Or is he just somebody that sits there?  
2 That's what I got out of that paragraph.

3 MR. RUETZ: He is the boss. He is the  
4 engineering officer of the watch.

5 MS. KOLB: We're wondering if perhaps you  
6 have an older revision of the -- of 7.6 -- or looking  
7 for --

8 MEMBER BROWN: Rev 2 is what I'm looking  
9 at. It's Rev 2. I thought I incorporated -- I spent  
10 half a day incorporating the proposed changes and  
11 strikeouts. I've got Rev 2. That's the only copy  
12 I've got.

13 MR. RUETZ: Yeah. So the supervisor  
14 workstation is essentially identical to those operator  
15 workstations. The part you might be focusing on is  
16 the fact that the supervisor station does not have the  
17 neutron driver console capabilities.

18 MEMBER BROWN: I don't -- that detail I  
19 don't have. It just said the supervisor can monitor  
20 system status but not control facility components. So  
21 he can't shut something down if he thinks it's out of  
22 control and somebody missed it. That one sentence,  
23 that's all I was talking about.

24 MS. KOLB: This is Catherine Kolb. We did  
25 find that sentence there. We will have to go back and



1 look at that. But the current design of the PICS  
2 system is that the supervisor station is identical to  
3 the operator stations.

4 We discussed that if maintenance needed to  
5 be performed on one of the regulator operator  
6 stations, you know, switching out monitors or such, it  
7 was unusable, that's -- the supervisor could use the  
8 backup. I think the intent of that was that the  
9 supervisor wouldn't normally be responsible for  
10 controlling equipment, but we can -- we can look at  
11 our wording there and make sure that's consistent.

12 MEMBER BROWN: It's just my concern,  
13 after, you know, 35 years of -- a number of crew  
14 quizzes, trials, qualification tests, watching  
15 operators on shifts, submarines, and aircraft  
16 carriers, the engineering officer of the watch, or the  
17 propulsion night watch officer on the carriers, while  
18 they weren't the main operators, if they thought their  
19 guys were screwing up somewhere, they could do  
20 something.

21 And I'm not advocating -- it's not the  
22 same. The spaces are much smaller, much more compact.  
23 This is -- and there's other people throughout the  
24 plant in those plants to do things. It's just having  
25 the supervisor, who supposedly really knows what's

1 going on, if he sees something, can he shut the stuff  
2 down, can he scram the plant. That's the thought  
3 process.

4 I just --

5 MS. KOLB: No.

6 MEMBER BROWN: I would just -- that's what  
7 that sentence implied to me, and it seemed to me that  
8 that station ought to be as capable as the operator  
9 workstations. He may not do anything because he  
10 shouldn't be. He should be supervising. But that's  
11 -- that was my thought process.

12 MS. KOLB: No. We appreciate the  
13 comments. The intent is that the supervisor station  
14 is the same as the operator stations.

15 MEMBER BROWN: Okay. Well, I'm sorry to  
16 have slowed -- slowed everything down here. I didn't  
17 know whether to address this when we got to the PICS  
18 discussions, but it -- once we got into this thing and  
19 I was listening, it seems like this was as good a  
20 place as any to at least get something on the record  
21 in the transcript. I'll never remember all the  
22 answers.

23 But I think you answered my question  
24 satisfactorily, and I appreciate your taking the time  
25 to do that.

1           Dennis, did you think I missed anything?  
2           I mean, you have a lot of operator experience  
3           yourself. You understand what I was looking for I  
4           think.

5           DR. BLEY: Yeah, I did. And I've seen the  
6           commercial plants when they went digital run into some  
7           problems like that that you couldn't quite tell what  
8           was going on. And then they started getting the  
9           operators involved in the design of those systems.

10          And the only one that kind of comes to  
11          mind here is if there are multiple stations that all  
12          do the same things, command and control could get lost  
13          somewhere, people start expecting the Joe on the other  
14          panel is going to do something, and then somebody else  
15          comes in on shift because Joe is sick, and you end up  
16          having things happen in the plant that you weren't  
17          expecting.

18          So there is a possibility of loss of  
19          control, I would think, but you'll have to work out  
20          the procedures for how those crews interact.

21          MR. RUETZ: Something I would like to  
22          volunteer that I think will alleviate some of your  
23          concerns here is the fact that those local stations  
24          that we mentioned previously outside of the control  
25          room, those stations normally can only have monitoring

1 capabilities. It's not until they typically check out  
2 the system from the control room, such that a prompt  
3 appears in the control room on those workstations that  
4 such-and-such a person is trying to check out a system  
5 to perform local operations. And the control room has  
6 to grant permission to that local station before any  
7 control capabilities are allowed.

8 MEMBER BIER: So this is Vicki Bier. What  
9 you just said taps into a question which I was going  
10 to ask, which is, what happens in the event that there  
11 is not necessarily anything going wrong in the plant,  
12 but there is a computer malfunction in the control  
13 room? And, you know, that could be because of cyber  
14 hacking. It could be just because of a hardware  
15 failure, something didn't boot properly, whatever.

16 So a two-part question. One, you know,  
17 does control automatically revert to the local  
18 stations in that circumstance? Or does the fact that  
19 the computer is down make it impossible to grant local  
20 control?

21 MEMBER BROWN: Let me --

22 MS. KOLB: This is Catherine Kolb. I  
23 guess it would depend on the failure, but, you know,  
24 if the failure was such that the PICS, you know,  
25 server or the entire network was down, then none of

1 the PICS systems would function.

2 MEMBER BROWN: Vicki, can I amplify?

3 MEMBER BIER: Please.

4 MEMBER BROWN: Okay. How many times did  
5 you get on your computer and you move your mouse and  
6 the pointer doesn't move? That's -- that's my biggest  
7 concern when people say we're controlling with mouse  
8 and keypads.

9 On the control systems that we did for the  
10 Navy, for multiple systems in the plant, we always  
11 have positive switch actuations for on/off,  
12 stop/start, what were the critical things you needed  
13 to do, increase frequency, what -- it was not -- not  
14 done with a touchscreen, not done with a mouse, and  
15 not done with a keyboard.

16 I only throw that out in that, you know,  
17 this is a critical facility, subcritical facility.  
18 You're irradiating things. And you've got a number of  
19 very critical systems that deal with some pretty  
20 hazardous materials.

21 And the last thing you want is an operator  
22 trying to control a system, and all of a sudden --  
23 this is stuff you're designing now with stuff that's  
24 out in the world. You're going to get stations, and  
25 you're using a mouse, and all of a sudden the sucker

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1 locks up. Forget the hacking. They will just do it  
2 for no reason at all.

3 And it happens -- like when we're on Teams  
4 and all of a sudden nobody knows I'm here because  
5 Teams disappeared for me. Okay? So you've got to be  
6 plugged back in.

7 So I'm just -- I am always very, very  
8 leery. You're going to do what you want to do. I  
9 just think for critical controls functions you might  
10 want to rethink, are there places where we want  
11 positive switch operation to start, stop, change  
12 certain critical operations that we're doing.

13 So I'd just put that on the table to let  
14 you know somebody is thinking about that from that  
15 standpoint.

16 MS. KOLB: No. I -- this is Catherine  
17 Kolb. I appreciate and understand your concern. A  
18 little commentary there. The safety actuations are  
19 pushbuttons. They are located on the main control  
20 board, so those are independent of the PICS software.  
21 So if it was necessary to shut down a unit, those are  
22 -- those are physical buttons and switches that are  
23 not related to the PICS that we do have.

24 And as for the reliability, it is -- it is  
25 the distributed digital control system, but it is --

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1 it is an industrial one that is used in other  
2 industrial facilities. And while it obviously can't  
3 fail, it is not safety-related, and it is not required  
4 to operate. But we've used, you know, reputable  
5 equipment in our -- in our design.

6 MEMBER BROWN: Yeah. I kind of gathered  
7 that, because I could see that at least for the TRPS  
8 and the ESFAS stuff we were looking at when you looked  
9 at the logic diagram and the words, there were  
10 literally on/off signals coming in via the hardware  
11 module and then over to the communication in order to  
12 do stuff.

13 But that is a system that is not a control  
14 system. You know, that's just the -- those two  
15 specifics. And I was thinking all of the other  
16 process systems as well. And if you -- if you're  
17 saying that you're using pushbuttons for -- I just --  
18 it's just I would encourage looking at all of those  
19 processes. You would be able to turn it on and off.

20 Or if there's a critical thing as you're  
21 ramping something, or doing whatever else, there were  
22 certain things that would be better to be done with  
23 what I would call more hand-eye coordination,  
24 mechanical, more like the potentiometer-type  
25 operation.

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1 I don't know how you would -- you know, in  
2 an old-time radio, which nobody even knows about  
3 anymore. I don't know why I said that.

4 DR. BLEY: Some of us do, Charlie.

5 MEMBER BROWN: Yeah.

6 DR. BLEY: But I'd mention something here.  
7 They've got the manual control -- direct manual  
8 control with the pushbutton switches on --

9 MEMBER BROWN: Yes.

10 DR. BLEY: -- key things. Now, a ship on  
11 the surface of the ocean and a submarine below the  
12 ocean, losing process control is a really, really bad  
13 thing. I think here, with the ability to shut down,  
14 shutting down is perfectly okay, and you don't put  
15 yourself in hazard because you tripped at all. But  
16 it's a little different.

17 MEMBER BROWN: No, I agree. It's --  
18 they've got lots of processes, and the TRPS and the  
19 ESFAS shut stuff down. And you have -- as long as you  
20 can do those things manually as well, with a  
21 pushbutton, not with a mouse, I think they are going  
22 to be in fairly decent shape. But just -- this is a  
23 very complex setup, and so that's why I was asking the  
24 question.

25 There's other conversation in the

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1 background. I don't know who it is, but it's coming  
2 through on my computer.

3 Anyway, that's -- I have exhausted my  
4 questions. So thank you very much.

5 MEMBER BIER: Okay. So getting back to my  
6 question, if there is a failure of a computer, is the  
7 expectation that everything would just be shut down or  
8 the control would revert to a local station?

9 MR. RUETZ: So, again, like Catherine  
10 mentioned, it would probably depend on the specific  
11 failure. So I will volunteer that the control room  
12 does have the ability to revoke those privileges that  
13 were previously granted to those local stations, such  
14 that -- it's always an issue with a local station or  
15 an operator at a local station. The control room  
16 could take back over control, so to speak.

17 MS. KOLB: Yes. And then to your question  
18 of --

19 MEMBER BIER: Yeah.

20 MS. KOLB: -- if the control room went  
21 dark and all of the screens went blank in some  
22 situation, so we would have procedures in place for  
23 what to do in that sense -- I don't have them in front  
24 of me, but my expectation would be that they would  
25 shut down the units because the operators wouldn't

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1 have any indication of what was going on.

2 MEMBER BIER: Got it. And are there also  
3 access to physical instruments at the local station so  
4 that there is monitoring of physical properties that  
5 doesn't have to go through the computer?

6 MS. KOLB: Yes. There are some parameters  
7 in the fields that are -- that don't have to go  
8 through the PICS, like especially in some of the  
9 utility systems. There are parameters that aren't --  
10 that you can walk up to locally.

11 MEMBER BIER: Yeah. Okay. Are there  
12 other questions for SHINE now? Because I also have a  
13 couple of questions for Jesse, but we've kind of  
14 gotten off track here.

15 MEMBER BROWN: I'm sorry. I'm --

16 MEMBER BIER: Well, that's okay. It's  
17 part of the job.

18 MEMBER BROWN: I'm sorry about that,  
19 Vicki.

20 MEMBER BIER: Okay. In that case, I'll  
21 offer my questions for Jesse. And if you want to  
22 postpone them or whatever, that's fine, too.

23 One, you said several times that SHINE is  
24 implementing what you called a limited human factors  
25 program. Can you talk about what some of the features

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1 would be in a more elaborate program for a plant that  
2 was counting on human action as part of the licensing  
3 basis?

4 MR. SEYMOUR: Yes. Absolutely. And,  
5 again, this is Jesse Seymour. So typically what we  
6 would see -- and this is what would come into play if  
7 we were looking at a plant that was covered by, you  
8 know, 50.34 Foxtrot 2II, which requires the state of  
9 the art of human factors engineering to be applied --  
10 we would see the application of NUREG, you know, 0711,  
11 right? So our human factors engineering guideline.

12 And what that would do is it would  
13 implement a process-based approach that consists of,  
14 you know, 12 individual steps, and that really -- it  
15 takes you through this full systems engineering-based  
16 design model where you -- you start with operating  
17 experience, task analysis, you know, functional  
18 requirements analysis, function and allocation, and  
19 you move through to the design of a human system  
20 interface.

21 And then from that step -- and, again,  
22 this takes into consideration factors like staffing,  
23 you know, training qualifications, and so forth.

24 And then once you've designed the human  
25 system interface, you move back through, you know,

1 sequentially verification and implementation work that  
2 culminates in integrated system validation. So  
3 typically, you know, you will put everything together  
4 and in a, you know, full scope simulator type of  
5 environment. You'll actually go through -- you know,  
6 put crews in there and make sure that things work, and  
7 then, you know, but there actually will be  
8 performance-based testing that does that.

9 So, again, for, you know, a facility that  
10 is obligated to apply the state of the art, that's  
11 what we -- we currently see as being the state of the  
12 art.

13 MEMBER BIER: Thanks. One other question.  
14 Oh, I guess two other parts. It sounds like from your  
15 description earlier that you have evaluated SHINE's  
16 human factors program, not the actual ergonomics  
17 engineering of specific displays.

18 So that if they implement their program  
19 properly, you have confidence that the displays will  
20 be reasonable and adequate, but that you haven't  
21 evaluated them specifically. Is that correct?

22 MR. SEYMOUR: That is correct. So in  
23 terms of, you know, doing a physical verification,  
24 that is not something that, you know, we have been  
25 able to do at this point.

1 MEMBER BIER: Right.

2 MR. SEYMOUR: What we have done is we have  
3 looked at, you know, the program and the process and  
4 the guidelines that are used. And provided that those  
5 guidelines are applied at the design and, you know,  
6 verify that the installation -- and that discrepancies  
7 are tracked, you know, that provides something that is  
8 akin to a design implementation and verification type  
9 of process that we would have seen with a more -- you  
10 know, a more developed human factors engineering  
11 program.

12 MEMBER BIER: Okay. And last question for  
13 you before at least I let you move on. You mentioned  
14 that you described the results of a quote/unquote  
15 "audit." And is that adequately captured in the SER,  
16 or is there a separate audit report that we should be  
17 trying to look at?

18 MR. SEYMOUR: So there is a separate audit  
19 report. And important thing to note is that there is  
20 a portion of the audit report that is proprietary, so  
21 there's a proprietary --

22 MEMBER BIER: Got it.

23 MR. SEYMOUR: -- attachment. And so we do  
24 -- we do touch upon, you know, a fair amount of that  
25 material, you know, within the SE, pointing to it.

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1           But I would -- you know, what I would say  
2           is that if you really want to get into the details of  
3           what we looked at kind of on a criteria-by-criteria  
4           and a -- you know, what standards were being used  
5           specifically --

6           MEMBER BIER:   Yep.

7           MR. SEYMOUR:   -- you know, within their  
8           HFE design guidelines, we'll really have to give you  
9           a proprietary copy of that audit report, so that you  
10          can see the fine detail. And that will get into even  
11          discussing, you know, the individual accident analysis  
12          sequences that we, you know, verified going through  
13          this. So --

14          MEMBER BIER:   Okay. Thank you.

15          MR. SEYMOUR:   Yep.

16          MR. BALAZIK:   This is Mike Balazik, NRC  
17          Project Manager for SHINE. I will send over the  
18          proprietary version to Chris Brown after this meeting.

19          MEMBER BIER:   Super. Thank you.

20          MEMBER BROWN:   Can I make one other  
21          observation, Vicki?

22          MEMBER BIER:   Yeah.

23          MEMBER BROWN:   Yeah. This is -- I just --  
24          and I didn't think about this when SHINE went through  
25          their stuff. I wanted to give them some credit. I

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1 like their categories of alarms where they show, you  
2 know, red light, yellow light, blue, and then kind of  
3 an information-type thing. So that's a good way to  
4 categorize stuff so as not to distract the operators.  
5 I mean, we did something similar relative to warnings  
6 as opposed to alarms in the program I worked in and  
7 Dennis observed on his ship.

8 The thing I would think about when you're  
9 doing that is don't have them show up in the same part  
10 of screens. There are -- all of the alarms ought to  
11 show up on the left, the mediums on the middle, and  
12 the -- you know, that's where I'm -- don't mix and  
13 match them in the same space, so that they don't get  
14 confused -- red, yellow, and blue.

15 So it's just a matter of how you lay out  
16 the screens. That's all. But it's a good idea to  
17 have a categorization, so you don't distract people  
18 with stuff that they can ignore for a while. That was  
19 just an observation. I wanted to give you credit.  
20 After beating you up, I thought I'd give you some  
21 credit for some good stuff.

22 MR. SEYMOUR: Okay.

23 MR. RUETZ: So I appreciate the credit, so  
24 thanks for that. One thing I will add to your comment  
25 is that one of the advantages of using this digital

1 interface that we have, as opposed to more analog-type  
2 alarms, is that our alarms are easily sortable, so we  
3 can sort by priority level, if necessary, or we can  
4 sort by time that the alarm has actuated. So those  
5 are different methods operators can use to diagnose  
6 the event that's in progress.

7 MEMBER BROWN: Got it. It certainly gives  
8 you capability. I agree with that. But many times  
9 the red light comes on and requires immediate action.  
10 You can't worry about sorting. You've got to go do  
11 something.

12 Okay. Thanks a lot. I appreciate it.  
13 Just wanted to say I wasn't trying to beat people up.

14 MR. SEYMOUR: Okay. Mike, could we move  
15 on to the next slide, please?

16 Okay. So in the next part of our  
17 technical evaluation we considered whether SHINE's  
18 administrative controls were adequately supported by  
19 their programmatic measures for the management of  
20 procedures.

21 We noted that specific administrative  
22 controls are incorporated into SHINE's procedures for  
23 implementation by facility staff. They noted that  
24 these procedures undergo review by management and are  
25 subject to provisions to ensure that they are

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1 technically accurate.

2 We also noted that procedures undergo  
3 verification and validation prior to use by operators.  
4 We found that the combination of processes used for  
5 the preparation, use, and management control of  
6 written procedures, the methods used for verifying and  
7 validating procedures before use, and the methods used  
8 for ensuring that current procedures are available to  
9 the facility personnel collectively supports the  
10 ability of SHINE operators to reliably implement  
11 administrative controls.

12 Next slide, please?

13 Finally, we considered whether SHINE's  
14 administrative controls were adequately supported by  
15 the programmatic measures for the training and  
16 qualification of operators. In reviewing this area,  
17 we noted that the licensed operator training programs  
18 include topics on both criticality control and  
19 management measures.

20 Additionally, we further noted that the  
21 training program is based upon a systems approach to  
22 training. Based upon this, we found that the  
23 combination of provisions for the initial training of  
24 personnel, personnel qualifications, and the  
25 retraining of personnel, supports the ability of SHINE

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1 operators to reliably implement administrative  
2 controls.

3 Next slide, please?

4 Based upon our review, we made the  
5 conclusions that are summarized here on this slide.  
6 First, we concluded that the human factors  
7 engineering-related aspects and programmatic  
8 considerations for the SHINE facility meet the human  
9 factors engineering-related aspects of Criterion 6,  
10 because within the specific context of the operator  
11 role and safety at the SHINE facility operators will  
12 reasonably be able to take actions to control the  
13 facility, be provided with controls designed to  
14 support safe actions, have sufficient knowledge about  
15 the status of the facility, be able to make decisions  
16 about the appropriate course of action given a  
17 particular operating circumstance, and be provided  
18 with the indications, displays, alarms, and controls  
19 that are designed to reflect their cognitive needs.

20 Second, we concluded that the human  
21 factors engineering design aspects of the SHINE  
22 facility control console and display instruments are  
23 acceptable because all nuclear and process parameters  
24 important to safe and effective operation of the SHINE  
25 facility will be displayed at the control console.

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1           The display devices for these parameters  
2           are easily understood and readily observable by an  
3           operator positioned at the facility controls. The  
4           controls are readily accessible, and the enunciator  
5           and alarm panels on the control console provide  
6           assurance of the operability of systems important to  
7           safe facility operation.

8           Furthermore, within the specific context  
9           of the operator role and safety of the SHINE facility,  
10          we concluded that the human system interface supports  
11          the manual initiation of protective actions for safety  
12          systems and provides displays and controls for manual  
13          actuation of safety functions and for monitoring those  
14          parameters that support them.

15          Finally, we concluded that the programs  
16          for procedures management and training and  
17          qualification are acceptable within the context of the  
18          operator role at SHINE for safety of the facility,  
19          because they reasonably support the ability of SHINE  
20          operators to reliably implement administrative  
21          controls at the facility.

22          So this concludes the prepared part of my  
23          presentation. I'd now like to ask if there is any  
24          additional questions from the committee.

25          MEMBER BIER: One additional question for

1 SHINE. Which vendor is doing your control designs?

2 MR. RUETZ: So RoviSys is the vendor that  
3 is doing our PICS design.

4 CHAIRMAN BALLINGER: Did we lose Vicki?

5 MEMBER BIER: I'm here. I have some audio  
6 problems.

7 CHAIRMAN BALLINGER: Yeah. There's some  
8 weird background stuff going on from somebody.

9 MEMBER BROWN: She's getting -- you're  
10 getting it also. We're getting a lot of feedback.

11 MR. BALAZIK: Yeah. This is Mike Balazik,  
12 NRC Project Manager. I think the feedback is coming  
13 from the SHINE leaving their mic open. We're getting  
14 an echo, and there also -- there is some sort of  
15 static that seems to be coming from SHINE.

16 CHAIRMAN BALLINGER: Well, the static just  
17 stopped. Well, I guess not.

18 MR. BARTELME: So is it -- so is it  
19 whenever SHINE is speaking or --

20 MR. BALAZIK: Yeah. Jeff, this is Mike.  
21 It's almost constant when SHINE gets on. There's a  
22 lot of static coming over.

23 DR. BLEY: And it's loud enough -- I'm not  
24 sure if Vicki heard the answer to her question, but I  
25 couldn't hear it through the static.

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1 MEMBER HALNON: I think SHINE needs to log  
2 off and log back in.

3 MEMBER BIER: I was able to hear the  
4 answer, Dennis. They said the contractor for the PICS  
5 system is NovSys.

6 DR. BLEY: Good.

7 MEMBER REMPE: It does seem to be better  
8 now. So perhaps it's cleared up.

9 MR. BALAZIK: Well, Dr. Rempe, they're not  
10 on -- they're not -- they're on mute right now.

11 MEMBER REMPE: Oh. That's why the  
12 static --

13 MR. BALAZIK: I guess that's why it  
14 improved.

15 CHAIRMAN BALLINGER: Okay.

16 MR. BALAZIK: Jeff, do you want -- go  
17 ahead, Professor. Sorry.

18 CHAIRMAN BALLINGER: No, no. What's up?

19 MR. BALAZIK: No. I was going to ask  
20 SHINE to see if they could unmute to see if the static  
21 is still there. They might be trying to rejoin the  
22 meeting because now I don't see them on.

23 CHAIRMAN BALLINGER: Well, that's -- they  
24 might be trying to fix it, but in any -- in any case,  
25 as I mentioned this morning, I have probably condemned

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1 myself to not being able to move faster when I said we  
2 were moving faster.

3 And so we now have a question to answer,  
4 and that is the next two presentations relate to the  
5 conduct of operations. And I'm hesitant to want to  
6 separate those two because I'm guessing that based on  
7 the questions and answers from the human factors part,  
8 I'm thinking that there is going to be a fair amount  
9 of crosstalk between those two. And so I'm not sure  
10 that it's a good idea to start the first presentation  
11 at 20 minutes 'til the hour and this go over and then  
12 have lunch.

13 So I'm proposing that we recess now until  
14 1:00, so that we can have those two sessions back to  
15 back. So are there any objections to that from  
16 members or the staff or SHINE?

17 MR. BALAZIK: This is Mike Balazik, NRC  
18 staff. No objections.

19 MEMBER BROWN: Do it. Do it, Ron.

20 CHAIRMAN BALLINGER: Okay.

21 MEMBER BROWN: This is Charlie.

22 MR. BARTELME: No objections from SHINE  
23 either. We were able to hop back on on Catherine's  
24 account. Were those last questions -- are there any  
25 follow-ups or were the members able to hear SHINE's

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1 response?

2 MR. BALAZIK: Yes. This is Mike Balazik.  
3 Can you just repeat the vendor for PICS one more time?

4 MS. KOLB: Yes. This is Catherine Kolb.  
5 So the vendor is RoviSys with an R. And that is a  
6 system integrator. The platform, the architecture, is  
7 an Allen-Bradley System.

8 MEMBER BROWN: By the way, your static and  
9 your reverberation has now gone away.

10 MS. KOLB: Excellent. We will use this  
11 computer going forward.

12 CHAIRMAN BALLINGER: I thought we might  
13 have had an electromagnetic block all of a sudden, or  
14 a pulse.

15 Okay. So we will now, assuming there are  
16 no other questions or comments from members,  
17 consultants, or others, we will recess until 1:00  
18 Eastern.

19 (Whereupon, the above-entitled matter went  
20 off the record at 12:41 p.m. and resumed at 1:00 p.m.)

21 CHAIRMAN BALLINGER: Okay. It's 1:00 p.m.  
22 We will now go back in session.

23 And the first presentation is from the  
24 SHINE folks on the conduct of operations. So I can  
25 see the slides. So let's proceed.

1 MS. KOLB: Thank you. This is Catherine  
2 Kolb. I'm the Senior Director of Plant Operations for  
3 SHINE. And I will be discussing conduct of operations  
4 this afternoon.

5 So, in this presentation, we are going to  
6 cover the topics of Chapter 12 that are, have not  
7 already been covered in other ACRS presentations. So  
8 that includes the organization, the review and audit  
9 activities, procedures, required actions and reports,  
10 and records.

11 So, starting with organization, this is a  
12 depiction of the normal organization chart for SHINE.  
13 This is not all the people that work for SHINE. This  
14 is a subset of those who are most directly involved in  
15 the operation of the facility. And I wanted to show  
16 this just to depict that, the wide range of people  
17 that are involved in making our facility run.

18 The next slide is the organization chart  
19 that is found in Chapter 12 and in our technical  
20 specifications. This describes the levels of the  
21 operations organization as defined in ANSI/ANS 15.1.

22 So we have the CEO and the diagnostics  
23 general manager comprising our Level 1 management.  
24 Level 2 is director of plant operations and the  
25 operations manager.

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1           Level 3 is the shift supervisor. So that  
2           is a senior licensed operator. And that person will  
3           be the most senior person at the facility, physically  
4           at the facility at any given time. That is not a  
5           single person. That is more of a role. So there will  
6           be a shift supervisor at the facility at all times.  
7           For example, we currently have four of them slated for  
8           that role. And they will rotate in that four-shift  
9           crew that we discussed previously.

10           The rest of the operators are comprising  
11           Level 4. So those are other senior licensed  
12           operators, licensed operators, and field operators,  
13           which is what we are calling our non-licensed  
14           operations individuals.

15           The philosophy for running the facility is  
16           that there will be one shift supervisor there at any  
17           given time. The licensed operators will be in the  
18           control room. And the non-licensed operators, field  
19           operators, or suitable technicians, those people will  
20           perform duties at the direction of licensed operators  
21           and under their cognizance.

22           The other organizations depicted on this  
23           slide are the review and audit committee, which we'll  
24           discuss in a little more detail in a couple of slides,  
25           and the radiation safety function, which is filled by

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1 the radiation protection manager, who was shown on the  
2 previous slide, and the radiation protection staff  
3 that work for the radiation protection manager.

4 Are there any questions on our  
5 organizational structure?

6 MEMBER SUNSERI: Catherine, this is Matt  
7 Sunseri. Do you have the quality assurance manager or  
8 director or something equivalent, and is that under  
9 the review and audit function? And if it will be  
10 discussed later, I can wait.

11 MS. KOLB: We do have quality assurance  
12 personnel. I did not show those on the normal org  
13 chart. They report to the Vice President of  
14 Regulatory Affairs and Quality. And there is a  
15 quality assurance manager that reports to that person  
16 and quality assurance staff. So that's -- you know,  
17 it's not shown, but it is part of our facility.

18 MEMBER SUNSERI: And do they have a dotted  
19 line to the Chief Executive Officer or something  
20 direct, some kind of direct access if they have to  
21 report there?

22 MS. KOLB: Yes, that, the org chart  
23 showing that relationship is in our quality assurance  
24 program description document.

25 MEMBER SUNSERI: Okay. Thank you.

1 MS. KOLB: All right. The next slide  
2 shows the minimum staffing. So this slide presents  
3 both the technical specification required individuals.  
4 Those would be the first three. And I presented it  
5 this way to show that we have other documents that  
6 drive us to have additional people at the facility in  
7 addition to the technical specification required  
8 roles.

9 So the shift supervisor, who I mentioned  
10 earlier, would be a senior licensed operator. And  
11 they are filling that role required in our technical  
12 specifications for having a senior licensed operators  
13 present at the facility or readily on call. They also  
14 fill the role of the emergency director described by  
15 the emergency plan, which we presented in a previous  
16 ACRS meeting.

17 We'll have at least one accelerator  
18 operator, who is a licensed operator. They could also  
19 be a senior licensed operator per the technical  
20 specifications. But either a licensed operator or a  
21 second senior licensed operator must always be present  
22 in the control room.

23 And in addition to that, we have an  
24 additional designated person. We expect that to be  
25 filled by either a non-licensed or an additional

1 licensed individual. But it could be anyone who is  
2 designated for that role and that fulfills our  
3 technical specification requirements.

4 In addition to the technical  
5 specifications staffing, the emergency plan drives us  
6 to have an additional person. That's individual  
7 number two, which we expect to be filled by a non-  
8 licensed operator as an additional accelerator  
9 operator or other designated individual to fill the  
10 role of emergency communicator, which we discussed in  
11 a previous ACRS meeting.

12 The emergency plan also drives us to have  
13 some individual with radiation protection experience.  
14 We expect that to be normally be filled by a member of  
15 the radiation protection staff. But it could be  
16 anyone who is trained and qualified for that role to  
17 be able to fill that radiation safety coordinator role  
18 identified in the E plan.

19 And then finally, we can't get into any  
20 details here, but we do have a physical security plan  
21 that prescribes requirements for security personnel.

22 So this slide is depicting the minimum  
23 staff that we would expect at any given time at the  
24 facility.

25 DR. BLEY: I'd like to ask you, this is

1 Dennis Bley, a question about authority. Who out of  
2 this cast of characters, including security, can  
3 direct the SRO to carry out specific operations in the  
4 plant?

5 MS. KOLB: The shift supervisor, who is a  
6 senior licensed operator.

7 DR. BLEY: Who can direct him to carry  
8 out, or her to carry out specific actions in the  
9 plant?

10 MS. KOLB: So they report to the  
11 operations manager.

12 DR. BLEY: Will the operations manager be  
13 licensed?

14 MS. KOLB: The operations manager will not  
15 be licensed.

16 DR. BLEY: But the operations manager can  
17 direct actions in the plant?

18 MS. KOLB: No. Everyone has a supervisor  
19 in our organization structure, but the shift  
20 supervisor is the senior licensed individual.

21 DR. BLEY: Okay. And that individual  
22 can't be overruled by other people in the  
23 organization.

24 MS. KOLB: No, not in terms of actions  
25 that affect the technical specifications or the

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1 operations of the facility.

2 DR. BLEY: I like that. Go ahead.

3 MS. KOLB: Were there any other questions  
4 about the minimum staffing for the facility?

5 All right. Moving on, this slide covers  
6 topics that are not in Chapter 12 but are topics that  
7 frequently come up when we discuss conduct of  
8 operations at a high level. So I just wanted to  
9 highlight a couple of topics that we do consider in  
10 that area.

11 So we have at SHINE a safety culture  
12 program, which emphasizes a commitment of safety over  
13 other competing goals and includes promoting a safety  
14 conscious work environment where people are encouraged  
15 to raise safety concerns, free to raise concerns  
16 without fear of retaliation.

17 We've defined in our internal programs a  
18 concept of operational authority, including who can  
19 manipulate controls, who can be present in the control  
20 area, which we've defined as the control room, and how  
21 to transfer operational authority between shifts  
22 during turnover. This ensures configuration control  
23 and awareness of the operations staff.

24 (Audio interference) look at conduct and  
25 professionalism for our operating staff. That

1 includes provisions for performance monitoring,  
2 guidance on assignment of duties in order to ensure  
3 the facility is safely and effectively operated.

4 We discussed training this morning. But  
5 that's -- and here is a bullet, because I wanted to  
6 reinforce the idea that training is not just the job  
7 of the training department. The operating staff owns  
8 their own training and participates with the training  
9 department to ensure people are qualified and able to  
10 do their jobs.

11 And then finally, procedures is discussed  
12 in a little more detail later. But procedures are  
13 just words. And without a commitment on how we're  
14 going to follow them, it doesn't mean much.

15 So our internal programs emphasize that  
16 procedure adherence is expected, that procedures will  
17 be complied with as written, with processes for what  
18 to do if a procedure cannot be executed as written.

19 And then operator aids aren't substitutes  
20 for poor procedures. But we do have provisions on how  
21 we will use and control them to ensure they're  
22 accurate and not detrimental to the staff.

23 DR. BLEY: Will the senior licensed people  
24 in the plant have a path through which they can  
25 deviate from a procedure if they believe it's

1 necessary for safety?

2 MS. KOLB: Yes, we have described that in  
3 our documents for procedure preparation and use on how  
4 to complete deviations and what is required in that  
5 process.

6 DR. BLEY: Okay. They don't need approval  
7 by more senior people outside of the plant?

8 MS. KOLB: No.

9 DR. BLEY: I know they'll have to defend  
10 themselves.

11 MS. KOLB: No, I believe we have, you  
12 know, rules for notifying and correcting the  
13 procedures after the fact. But, no, they will be able  
14 to deviate if necessary in accordance with our  
15 processes.

16 DR. BLEY: Thanks for that clarification.

17 MEMBER BIER: Yeah, I just wanted to  
18 emphasize that that's important, because, in fact, in  
19 many cases, verbatim compliance with written  
20 procedures can actually be used as a stop work  
21 mechanism. So it may not always be possible to follow  
22 the procedures as written.

23 MS. KOLB: Thank you for that. Yeah, we  
24 do have that, those provisions. But in absence of  
25 other direction, we do expect our staff to follow

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1 procedures as written, but understand the concern  
2 there.

3 Moving on to the next slide, so we have  
4 established at SHINE a review and audit committee that  
5 is described in Chapter 12 and in our technical  
6 specifications. It defines the minimum membership.

7 The chair is the diagnostics general  
8 manager, one of our Level 1 individuals or designee.  
9 And then the membership of the committee includes  
10 people with experience in engineering, operations, and  
11 radiation protection.

12 The charter includes provisions where we  
13 can use non-SHINE employees, especially when the  
14 required expertise is not available from SHINE  
15 employees.

16 And it's a requirement that facility  
17 operations personnel, which would be people reporting  
18 up through the director of plant operations, which  
19 from the original org chart includes the operations  
20 department, the maintenance department, and the  
21 chemistry department, those people cannot constitute  
22 a majority on the review and audit committee.

23 MEMBER HALNON: So this is Greg. Given  
24 the facility's makeup of chemicals, why wouldn't that  
25 chemistry manager not be a required minimum

1 membership?

2 MS. KOLB: The engineering and the  
3 operations individuals are expected to have experience  
4 in our facility, which, as you mentioned, is, has the  
5 radioisotope production facility portion.

6 The chemistry manager is important. But  
7 they are mostly in charge of the lab reporting,  
8 specifically for doing testing and other required  
9 things, both technical specifications and for our  
10 product. But we believe that the engineering and the  
11 operations experience should encompass that.

12 MEMBER HALNON: Okay. I guess we'll agree  
13 to disagree. I think that the chemistry manager is  
14 integral to the facility such as this, being the  
15 unique nature of it. But I understand where you're  
16 coming from.

17 MS. KOLB: I mean, there are provisions in  
18 our charter for including people with expertise,  
19 especially if we were doing an audit of some area that  
20 had particular chemistry expertise that was required  
21 of being able to assign people to that. They would be  
22 able to perform that function and not be limited to  
23 just these three people.

24 DR. BLEY: Let me push a little bit on  
25 this if I can. I'm Dennis, again.

1           One of the things this committee might be  
2     reviewing is a change to the facility, come in, cut  
3     some parts out, put some new things in. Not having a  
4     chemical process engineer -- I mean, I'm sure you had  
5     them during the design of this system. And we've  
6     talked about that a long time ago. Not having a  
7     chemical process engineer to confirm that the changes  
8     aren't going to lead to some kind unexpected problem  
9     seems I would say shortsighted.

10           We've seen lots of incidents in nuclear  
11    plants and other facilities where changes to the  
12    system have led later to problems because the people  
13    involved in the change didn't fully understand the  
14    functions that could lead it into problem areas. So  
15    I guess I'll be like Greg and agree to disagree.

16           MS. RADEL: This is Tracy. I want to  
17    clarify, you know, the engineering team members is  
18    where the chemical process engineers would be. You  
19    know, the chemistry department is checking and  
20    verifying, you know, the parameters of the different  
21    streams, whether it be target solution or waste  
22    streams.

23           But as far as system design or changes to  
24    design or how you operate the equipment, engineering,  
25    including chemical process engineers, would be

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1 involved in reviewing that and ensuring that it's  
2 appropriately considered in the system design, as well  
3 as the safety analysis.

4 DR. BLEY: That's what I was looking to  
5 hear. So they, the chemical process guys, folks show  
6 up under engineering and would participate depending  
7 on what kind of review you're doing.

8 MS. RADEL: Correct.

9 MS. KOLB: That is correct. And the --  
10 this is Catherine. And the -- this is just the review  
11 and audit committee requirements here. SHINE has  
12 processes for preparing and reviewing and approving  
13 individual engineering documents in addition to this.

14 So we're viewing this as a check of, you  
15 know, other things. This isn't the only review of  
16 documents that come before them. There are other  
17 processes we have in place.

18 DR. BLEY: Okay. But this is a review,  
19 and sometimes those kinds of committees spot the  
20 problems that the people involved don't see because  
21 they're looking towards success of what they're  
22 designing. And these folks might be looking to find  
23 ways that might not work right. So you don't always  
24 get that in those reviews along the way.

25 MS. KOLB: Understand.

1                   MEMBER SUNSERI: Hey, Catherine, this is  
2 Matt Sunseri. I had a question about this  
3 organization. I've been studying it a little bit  
4 here. To me, this review and audit role, function  
5 committee appears to be what I'm going to call a  
6 hybrid of two classical organizations.

7                   One is a station review and oversight  
8 committee comprised of these kind of people like you  
9 described here to look at the things that we've been  
10 talking about. Some call them operations review  
11 committee, station operation committee. They come  
12 under a variety of names. The audit function appears  
13 to be a quality assurance part, performing audits  
14 independently.

15                  So do I have that kind of straight, or can  
16 you clarify that for me?

17                  MS. KOLB: Yes. You can move to the next  
18 slide, Jeff.

19                  So this committee is following the model  
20 specified in Research Reactor Standards 15.1. But  
21 you're right on how we intend to implement it.

22                  So the review function, you know, is  
23 similar in the way that we're envisioning it to, you  
24 know, and then an oversight committee responsible for  
25 these items listed in the first major bullet here.

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1           The audit function, we do have quality  
2 assurance departments that we intend to use and take  
3 credit for as part of this to delegate to the actual  
4 performance of audits to them when possible, whenever  
5 we can. The -- but, yes, that is a QA function, as  
6 they both feed well to, in many if not all of the  
7 audits that we specified here.

8           MEMBER SUNSERI: So are the actual quality  
9 assurance audits performed by independent team members  
10 and this is, this committee is just providing an  
11 oversight of those audit results, or are these, is  
12 this committee somehow involved in the production  
13 activity of performing the audit? My question is  
14 really trying to get at the independence of the  
15 quality assurance function from production activities.

16           MS. KOLB: The attempt is to not have to  
17 independently audit, you know, for example, the  
18 emergency plan by two different independent  
19 organizations.

20           So, if the quality group leads an audit of  
21 the emergency plan because they have no involvement in  
22 the emergency plan and they do it for their prescribed  
23 frequency, they would do it, you know, in conjunction  
24 with or at the direction of the review and audit  
25 committee as part of their required audit list and to

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1 take credit for that, because they would also be  
2 independent of that program.

3 I don't know if that answers your  
4 question.

5 MEMBER SUNSERI: So just let me throw out  
6 a hypothetical situation as far as an example maybe.

7 So let's say that the quality, that you  
8 were performing an audit of the technical  
9 specifications. And we find some deficiency in the  
10 way the tech specs are being implemented or tested or  
11 whatever, right, the quality assurance finding. Can  
12 the operations member of this review and audit  
13 committee overrule that finding?

14 MS. KOLB: No, for a couple of reasons.  
15 They can't constitute a majority of the review and  
16 audit committee. So that member wouldn't have that  
17 power to overrule. And if we got to the end of an  
18 audit, the charter describes how audits work, that  
19 they would, you know, commission the audit, and then  
20 they review the results of.

21 So I'm not really seeing the opportunity  
22 to overrule the results of the audit when it's just  
23 being presented for a review I guess.

24 MEMBER SUNSERI: Okay. So, I mean, I  
25 understand what you're saying. I guess I just --

1 between this and my previous comment about where the  
2 QA manager reports, I just kind of see a lack of  
3 visibility of the importance of the quality assurance  
4 role.

5 I mean, the review and audit committee  
6 doesn't have a quality assurance member on it. The  
7 audit function is kind of mixed in with operational  
8 activities. The quality assurance manager doesn't  
9 show up on the organizational chart.

10 It just -- I know it's not the case. But  
11 it just appears to be a lack of high visibility of the  
12 importance of that function. So I'll just leave it as  
13 a comment.

14 MS. KOLB: I appreciate the comments. I  
15 mean, the org chart at the beginning of this  
16 presentation is a subset that is not actually in this  
17 document. I created it specifically for this  
18 presentation. The quality assurance people do exist  
19 in the formal org chart.

20 MEMBER BIER: So one other question. This  
21 is Vicki Bier. In terms of any major plant changes,  
22 upgrades, modification, et cetera, is there a  
23 procedure to document both the analysis that led to  
24 that and, you know, a committee review or whatever  
25 that approved the change?

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1 MS. KOLB: The engineering department has  
2 procedures and requirements for documenting their  
3 engineering outputs, calculations and drawings and the  
4 packages, design packages. So that would be the  
5 documentation of the analysis there.

6 And then the documentation of this  
7 independent, this extra review by the review and audit  
8 committee, that is documented by memos that are  
9 distributed within three months of the meeting where  
10 it was reviewed.

11 MEMBER BIER: Okay. So, for instance, if  
12 engineering made a recommendation and it was decided  
13 to depart from that or engineering put forward three  
14 options and they decided to go with number two or  
15 whatever, that would be documented someplace, the  
16 reasoning for that.

17 MS. KOLB: Yes.

18 MEMBER BIER: Thanks.

19 MS. KOLB: All right. So we've discussed  
20 the function of the committee a little bit. But just  
21 to reiterate they have a review function, which is  
22 based on the topics that are provided in research  
23 reactor ANSI standards, in some cases modified  
24 slightly to be applicable to SHINE.

25 And the audit function, they will audit

1 facility operation for conformance to technical  
2 specifications, training programs, or resulted  
3 corrective actions, and various facility programs and  
4 plans, including the emergency plan, radiation  
5 protection plan, the physical security plan, nuclear  
6 criticality safety program, and a few others.

7 Next slide. On this slide, we're talking  
8 about procedures. So Kris covered earlier in the day  
9 a process for verifying, validating them. But just to  
10 reiterate, we have a defined process for preparing,  
11 reviewing, approving, verifying, and validating  
12 procedures that provide direction for normal,  
13 abnormal, and emergency situations.

14 The topics that must be covered by  
15 procedures are included in this list. This list is  
16 based on one that is found in ANS 50.1, modified  
17 slightly to be applicable to the SHINE facility. That  
18 list was very reactor based, so we changed some of the  
19 terminology there.

20 Next slide. So this next slide combined  
21 required actions and reports. The -- a little bit of  
22 an echo there. But to put it in context, I've listed  
23 the safety limits there.

24 So we have defined safety limits in our  
25 technical specifications. And the required actions to

1 be taken in the event of a violation of a safety limit  
2 are to shut down facility operations immediately, and  
3 operations shall not be resumed until authorized by  
4 the NRC.

5 Reporting such event to Level 2  
6 management, which is the operations manager or the  
7 director of plant operations and the NRC. And there  
8 is a report that is prepared, reviewed by the review  
9 and audit committee, and submitted.

10 Other required actions on the next slide  
11 relate to other special reports. So those are also  
12 defined in our Chapter 12 and in our technical  
13 specifications, so events such as release of  
14 radioactivity above limits, operations with the safety  
15 system settings less conservative than required,  
16 violation of LCOs established in our technical  
17 specifications, and other events listed here.

18 Actions that we would take on the  
19 occurrence of an event that requires a special report  
20 would be to shut down the affected areas for the  
21 processes, and operations shall not be resumed until  
22 authorized by Level 2 management. And it should be  
23 reported to Level 2 management and the NRC, the  
24 occurrence reviewed by the review and audit committee.

25 So these activities here, these events

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1 that might occur require a special report as shown in  
2 Chapter 12.

3 We also, on the next slide, identify a  
4 couple of other reports. So we have operator reports  
5 that are required, including operating experience for  
6 future radiation units, any unscheduled shutdowns or  
7 corrective actions, tabulation of major changes,  
8 summary of affluence and other environmental surveys,  
9 and individual monitoring results required by 10 CFR  
10 20.1502.

11 There are other special reports defined,  
12 including permanent changes in Level 1 or Level 2  
13 management and any significant changes in our  
14 transient or accident analysis described in the FSAR.

15 We've also identified additional event  
16 recording as required by 10 CFR 70.50 and 52 and a set  
17 of requirements that are specific to SHINE but that  
18 meet the intent of Appendix A to 10 CFR Part 70.

19 And finally, after the completion of the  
20 startup testing, we specify that we will submit a  
21 startup report.

22 And the next slide, final slide, is  
23 records. So we've defined in Chapter 12 and in the  
24 technical specifications a number of records that the  
25 SHINE facility will maintain.

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1           We have lifetime records related to  
2           affluence, environmental surveys, radiation exposure,  
3           drawings of the facility, and records of reportable  
4           occurrences as listed there.

5           We've defined a number of five-year  
6           records related to facility operations, maintenance,  
7           other reportable occurrences, and the list as shown.  
8           And finally, records that are only required to be  
9           retained for one rated survey (audio interference)  
10          radiation cycle related to training of licensed  
11          operators.

12           And this is the end of my prepared slides.  
13          Are there any additional questions?

14           CHAIRMAN BALLINGER: Yeah, this is Ron  
15          Ballinger. So the ultimate authority during the  
16          normal operation of the plant is the shift supervisor,  
17          right?

18           MS. KOLB: Correct.

19           CHAIRMAN BALLINGER: So, if an abnormal  
20          occurrence occurs, it doesn't necessarily have to be  
21          an alarm or, something which fits into one of your  
22          categories which would require the plant to be shut  
23          down or returned to a normal, if you want to call it  
24          that, condition right away, is there a set of  
25          conditions where you don't have to go through the

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1 shift supervisor to shut the plant down?

2 MS. KOLB: Yes. Any licensed operator has  
3 the authority to shut down the facility in accordance  
4 with their license if they believe that it is unsafe.

5 CHAIRMAN BALLINGER: Okay. So they don't  
6 have to track down the shift supervisor every, if  
7 something, if it's a bad hair day.

8 MS. KOLB: Hopefully they won't be  
9 shutting down the facility for a bad hair day. But,  
10 yes, they have, per their training and their license,  
11 the authority to shut down the facility if they deem  
12 it necessary.

13 CHAIRMAN BALLINGER: Thank you. Other  
14 questions from members or consultants?

15 Thank you, then. So can we shift over to  
16 the staff side?

17 MR. LYNCH: Good afternoon. I just want  
18 to -- this is Steve Lynch, the Chief of the Advanced  
19 Reactor Policy Branch. Before I begin with the NRC  
20 staff remarks, I just want to confirm that everyone  
21 can see my first slide on the screen.

22 MR. LYNCH: Okay then, I will get started.  
23 So this is the NRC staff's review of SHINE's conduct  
24 of operations looking at Chapter 12, Sections 12.1-  
25 12.6.

1           This is largely an administrative portion  
2 of our review as we look at the levels of organization  
3 within the SHINE facility, including reporting the  
4 communication lines, review and audit activities,  
5 procedures, required actions, reports, and maintenance  
6 of records.

7           So as we conducted this review, there are  
8 a core set of regulatory requirements that we looked  
9 at to ensure that SHINE was meeting necessary  
10 requirements. 10 CFR 50.34 and paragraph B6 includes  
11 the requirements for describing the organizations of  
12 the facility.

13           Requirements 10 CFR 50.40 and 50.57  
14 provide general findings for the NRC staff to make  
15 regarding the technical qualifications of the  
16 applicant to be able to carry out activities within  
17 the facility.

18           The conditions of licenses paragraphs in  
19 10 CFR 50.54, specifically paragraphs I, J, K, L, and  
20 M-1 discuss minimum staffing requirements at the  
21 facility. And 10 CFR Part 20 provides requirements  
22 for the standards for protection against radiation.

23           So in implementing these regulatory  
24 requirements, the NRC staff starts with NUREG 1537,  
25 our standard review plan for non-power reactors, as

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1 augmented by our interim staff guidance to include  
2 aqueous homogeneous reactors and radioisotope  
3 production facilities. So that is the main guidance  
4 that is applicable to SHINE.

5 And within this there are two ANSI  
6 standards that we primarily evaluated the information  
7 in SHINE's application against for these sections, and  
8 that is ANSI/ANS 15.1, the development of technical  
9 specifications for research reactors. And ANSI/ANS  
10 15.4, selection and training of personnel for research  
11 reactors.

12 So in comparing the information SHINE  
13 provided in the FSAR, as they described in their  
14 presentation a few minutes ago, they generally  
15 followed the guidance in both ANSI/ANS 15.1 and 15.4,  
16 which is consistent with the information needs that  
17 the NRC staff has in NUREG 1537 to satisfy those  
18 applicable regulatory requirements that I just  
19 mentioned.

20 For this presentation, since largely SHINE  
21 adopted the direct language from the ANSI standards,  
22 I do want to just highlight some of the exceptions  
23 that SHINE took to the -- to the standards that the  
24 NRC staff found to be acceptable on account of its  
25 specific design considerations or operations of the

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1 SHINE facility that are different from being a  
2 research or test reactor.

3 Primarily, this looks at how SHINE has the  
4 irradiation units containing an aqueous target  
5 solution, the commercial nature of the facility, and  
6 the production facility that SHINE is operating.

7 So over the next two slides I'll just  
8 quickly go over some of the exceptions that SHINE took  
9 to the ANSI standards and why the NRC staff found  
10 these to be acceptable. And looking at Section 12.2  
11 in the review function and audit function paragraphs,  
12 SHINE had excluded looking at the review of  
13 experiments at the facility.

14 So experiments are included in these ANSI  
15 standards because at research reactors there are often  
16 in-core experiments being conducted that are separate  
17 from standard operations of the reactor.

18 Since SHINE is a commercial medical  
19 radioisotope facility and not a research reactor, they  
20 will not be conducting any of these experiments as a  
21 research reactor would. So it is acceptable in this  
22 section and in other sections that I'll highlight that  
23 SHINE has excluded experiments from consideration.

24 Also, with the audit function, SHINE has  
25 included additional elements within its audit function

1 that go beyond the minimum provided in the ANSI  
2 standard.

3 So in its audit function, SHINE has  
4 included its quality assurance program description,  
5 its physical security plan, and nuclear criticality  
6 safety program within the scope of items that may be  
7 audited. So since this goes beyond the minimum, the  
8 NRC staff finds that acceptable.

9 So again, when we're looking at Section  
10 12.3, SHINE did modify what it looks at for topics for  
11 which written procedures are prepared, reviewed, and  
12 approved. They modified the language in here slightly  
13 to deviate from the reactor-centric language to follow  
14 closely with the technology that they have for  
15 irradiation units and the associated target solution  
16 in place of a reactor fuel that they would have.

17 Again, this was another example of an area  
18 where SHINE will not have any written procedures  
19 associated with this experiments since they will not  
20 be conducted at the facility.

21 And in Section 12.4, SHINE again, as in op  
22 (phonetic) being a reactor, used broader language to  
23 encompass looking at operations and processes both  
24 within the irradiation facility and the radioisotope  
25 production facility as being within the scope of

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1 reportable events and actions to be taken should a  
2 reportable event occur.

3 And with this section, I'll just note that  
4 SHINE did highlight for the radioisotope production  
5 facility in their presentation that they are looking  
6 at the requirements for reporting in 10 CFR Part 70 as  
7 appropriate for events that affect a licensed  
8 material.

9 And then in the final two sections of  
10 Chapter 12 covered in this portion of the  
11 presentation, for annual operating reports, they were  
12 -- there were two deviations that I wanted to  
13 highlight that the NRC staff found acceptable. This  
14 is the exclusion of tests or experiments from  
15 reporting to the NRC as SHINE does not have these.

16 And then also SHINE did have a more  
17 conservative approach to providing results of  
18 individual monitoring carried out for individuals for  
19 whom monitoring is required by 10 CFR 20.1502. By  
20 following -- by reporting the monitoring results in  
21 alignment with this regulatory requirement, it is more  
22 conservative than what the ANSI standard requires.

23 According to the ANSI standard, reports  
24 would only need to be prepared if the doses that are  
25 contained in Part 20 are exceeded by greater than 25%.

1 So SHINE has done away with that threshold and is  
2 reporting down at just the regulatory requirements for  
3 monitoring. It will report out on those. So because  
4 that is more conservative, the NRC found that  
5 acceptable.

6 And then in Section 12.6, for records to  
7 be maintained at the facility, again, only two  
8 exceptions for experiments, and then also SHINE has  
9 modified the language to be more broad. It's in place  
10 of heterogeneous reactor fuel, they will have  
11 radioactive material inventories associated with the  
12 target solution they will have at the facility.

13 So they have used that appropriate  
14 language to be all-encompassing of records that need  
15 to be maintained related to that material.

16 So these next few slides just are a  
17 summary of the findings that the NRC staff has made.  
18 In general, because SHINE closely followed the  
19 information in ANSI standards 15.1 and 15.4, the NRC  
20 staff was able to make all of the necessary findings  
21 that were in NUREG 1537, Vol. 2, as augmented by the  
22 interim staff guidance to satisfy appropriate  
23 regulatory requirements.

24 So the organizational structure. As SHINE  
25 had presented on their slide, that is consistent with

1 what is in the ANSI standard and it gave the NRC staff  
2 confidence that there is a complete organization of --  
3 all the way down from the operations staff up to the  
4 ultimate license holder.

5 More detailed descriptions of each of  
6 these positions were provided in the FSAR such that  
7 the NRC staff could understand their responsibilities  
8 in relationship to one another.

9 This has also given us confidence that the  
10 responsibility for the safe operation of the facility  
11 and for the protection of the health and safety of  
12 both the SHINE staff and members of the public have  
13 been demonstrably shown.

14 SHINE went over their staffing for minimum  
15 staffing at the facility, from shift supervisors that  
16 also serve the function of a senior reactor operator  
17 and other licensed operators at the facility. All of  
18 that satisfies the requirements in 10 CFR 50.4 for  
19 minimum staffing. And also then supports the review  
20 that the NRC staff did separately on meeting the  
21 operator requirements in 10 CFR Part 55.

22 For each of the personnel that are  
23 described, SHINE has provided a list of the necessary  
24 experience, education, and training that needs to be  
25 provided for each of those individuals. And also

1 SHINE has made a commitment within the FSAR to follow  
2 the radiation training requirements that are in 10 CFR  
3 19.12. This is also consistent with expectations that  
4 are set in the ANSI standards.

5 SHINE has also described the radiation  
6 safety organization that is acceptable. As we saw in  
7 their pictorial organization graph, the organization  
8 has direct access to upper management in the review  
9 and audit committee to express concerns if necessary.  
10 As we saw, that was highlighted by some of the audit  
11 communication lines to ensure that there is access  
12 outside of direct reporting.

13 And we also have confidence that the  
14 radiation safety staff has the authority to interdict  
15 and terminate activities to ensure safety.

16 So additional findings that the NRC staff  
17 made. The Review and Audit Committee members appear  
18 to be well-qualified, with a wide spectrum of  
19 expertise. The Committee membership includes  
20 provisions for including persons from outside.

21 To follow up on the conversation that we  
22 had during SHINE's presentation of this, the NRC staff  
23 is comfortable with the minimum staffing provided for  
24 the Review and Audit Committee and that there is  
25 sufficient flexibility and commitment to bring in the

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1 necessary technical expertise out of those minimum  
2 staffing to address specific issues on an as-needed  
3 basis.

4 And the general descriptions, for example  
5 with engineering, are broad enough to encompass  
6 various disciplines such as chemical processing to  
7 address review and audit needs for the facility.

8 SHINE has proposed a charter and rules  
9 that describe the number of times the Committee meets,  
10 the way the Committee conducts business, the  
11 requirements for a forum when voting, and the way the  
12 Committee distributes its reports and reviews.

13 SHINE has proposed a comprehensive  
14 acceptable list of items that the Committee will  
15 review and audit. As I mentioned earlier, SHINE has  
16 gone beyond the minimum suggestions in ANSI 15.1 on  
17 the items that are included within the review and  
18 audit list of document.

19 SHINE has proposed a set of required  
20 procedures as appropriate to operation of the  
21 facility, and that the process and method described by  
22 SHINE will ensure proper management control and proper  
23 review of procedures.

24 And then for our last slide here, SHINE  
25 has defined a group of incidents as reportable events

1 and has described the required actions it will take if  
2 the reportable events occur. The definition of  
3 reportable events gives reasonable assurance that  
4 safety-significant events will be reported by the  
5 applicant.

6 I think this is especially true since  
7 SHINE taking into consideration the production  
8 facility that they will be operating has looked to 10  
9 CFR Part 70 for licensed material reportable events  
10 that are separate that they might see at the  
11 irradiation units and has included this as part of  
12 their reportable events.

13 So I believe that they have taken the  
14 necessary look and been comprehensive in defining what  
15 reportable events need to be included for the  
16 facility.

17 SHINE has proposed actions to be taken if  
18 the safety limit is violated or a reportable event  
19 occurs. The NRC staff has determined that SHINE will  
20 take whatever actions are necessary to protect the  
21 health and safety of the public.

22 So this goes back to what SHINE had said,  
23 that operators and senior operators at the facility  
24 are able to take the actions that are necessary to  
25 ensure the safe operation or shutdown of the facility.

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1           We had briefly touched on deviations, you  
2 know, if an operator needs to make decisions that are  
3 outside of what might be prescribed. ANS 15.1 does  
4 provide for temporary deviations from procedures that  
5 may be made by the responsible senior operator or  
6 higher individual present in order to deal with  
7 special or unusual circumstances or conditions.

8           Such deviations shall be documented and  
9 reported within 24 hours or the next working day to a  
10 level 2 or designated alternates. That is what is  
11 included in ANSI 15.1 for deviations that may be made  
12 by operators and SHINE has committed to implementing  
13 that in the FSAR.

14           SHINE has described the content, the  
15 timing of submittal, and the distribution of reports  
16 to ensure that important information will be provided  
17 to the NRC in a timely manner.

18           And finally, SHINE has described the types  
19 of records that will be retained by the facility and  
20 the period of retention to ensure that important  
21 records will be retained for an appropriate time.

22           And in SHINE's presentation they provided  
23 some lists of these documents and reports. And all of  
24 that is consistent with what is found in ANSI 15.1.

25           So that concludes my prepared remarks, and

1 I'm happy to address any questions that the members  
2 may have.

3 DR. BLEY: Yeah, Steve, this is Dennis  
4 Bley. I was unhappy with the way you began this  
5 presentation, saying this stuff was all primarily  
6 administrative. Well, there's lots of administrative  
7 requirements here.

8 But if you don't think the things we were  
9 talking about earlier, such as what can licensed  
10 operators do, who can overrule licensed operators,  
11 that sort of thing is important to safety, you and  
12 your colleagues simply haven't read enough reports of  
13 bad events in plants. I really wish you didn't  
14 introduce it that way.

15 MR. LYNCH: I appreciate that. I will be  
16 more careful with my word choice in the future.

17 MEMBER BIER: One question or comment,  
18 Vicki Bier here. You mentioned that there was no need  
19 to report experiments because this is not a research  
20 reactor, which is certainly the case.

21 But it occurs to me that there may still  
22 be still be experiments broadly defined if the plant  
23 is considering, for example, a change in operating  
24 procedures or chemistry parameters or whatever.

25 There may be some out-of-normal operation

1 that's undertaken deliberately before making a final  
2 change or whatever. And I assume there is a mechanism  
3 of reporting of that, even though it's not a formal  
4 scientific experiment. But can you comment on that  
5 briefly?

6 MR. LYNCH: Yeah. So as we're talking  
7 about -- you know, SHINE would need to make -- would  
8 need to report on that unless whatever -- I don't want  
9 to use the word experiments since they said they  
10 wouldn't be doing that.

11 But if there are some sort of processes or  
12 operations that they're doing, they would need to  
13 report that to the NRC and possibly look at 10 CFR  
14 50.59 to see if it fits with any change that is being  
15 made to the facility that can be done without a  
16 license amendment, or is it a change to the facility  
17 that they would need to come into the NRC for us to  
18 review and approve before they conduct that.

19 MEMBER BIER: I guess I'm thinking of  
20 things that may not even require a 50.59 approval but  
21 may still be kind of outside of, you know, deviation  
22 from normal operating procedure or something. And is  
23 there a mechanism or is that entirely within their own  
24 -- it doesn't require an approval for the change?

25 MR. LYNCH: Sure. So there are some --

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1       there are some descriptions within the -- within the  
2       deviations covered for procedures that SHINE has at  
3       the facility. And as part of our review, we did look  
4       at how -- does SHINE have a mechanism in place to  
5       appropriately modify or deviate from procedures and  
6       how that is reported. So they do have that mechanism  
7       in place.

8               Also, should there be changes in  
9       procedures, the NRC staff does have the opportunity as  
10      we conduct our oversight program and inspections to  
11      look at procedures when we are on -- we are on site to  
12      see how they have been carried out and if it's been  
13      done appropriately at the facility.

14             MEMBER BIER: Okay, thank you.

15             CHAIRMAN BALLINGER: Other questions from  
16      members or consultants? Well, thank you then.

17             Our last subject for the day will be the  
18      startup plan and so can we -- let's transition over to  
19      the SHINE folks, please.

20             MR. DRURY: Can everyone see the slides?

21             CHAIRMAN BALLINGER: Loud and clear.

22             MR. DRURY: Hello, everybody, this is Tom  
23      Drury, the Commissioning Coordinator for SHINE. I'll  
24      talk to you about the startup plan.

25             We'll start with the purpose of the plan,

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1     how we're going to administer the plan, a description  
2     of the facility tests, and then the radiation unit  
3     tests.

4             So the startup testing is conducted to  
5     ensure that the as-built facility confirms to the  
6     design and that the specified safety functions of  
7     systems, structures, and components are achieved.

8             To do this, we're going to verify key  
9     parameters that are necessary for the safe operation  
10    of an irradiation unit, and also the key parameters  
11    necessary for the safe handling of special nuclear  
12    material outside of an IU.

13            We will also be ensuring that the  
14    operating characteristics of the facility are well  
15    understood, including confirming calculational  
16    parameters and also establishing operational  
17    parameters, including set points.

18            We will do this to ensure that the safety  
19    of the plant is not dependent on the performance of  
20    untested SSCs during normal operation. And we will  
21    also structure the testing in such a way that during  
22    testing, we're never testing with untested SSCs. Next  
23    slide.

24            The administration of the testing. So we  
25    will perform testing in accordance with approved test

1 procedures and test plans. Within those plans, we  
2 have predetermined acceptance criteria. The execution  
3 of each of these tests will be led by a qualified test  
4 lead and additional test personnel.

5 During the testing, deficiencies will be  
6 documented and dispositioned. And following testing,  
7 a startup test report will be written.

8 For each test, we'll outline the methods  
9 and objectives of the test, have a comparison with  
10 acceptance criteria, discuss design and construction  
11 deficiencies and how to address those, justification  
12 for any of the nonconformances, a summary of the  
13 results of the test. And overall that report will be  
14 submitted within six months of the completion of  
15 testing activities.

16 So turning to the facility tests. These  
17 are tests that are conducted to verify operation of  
18 systems outside of IU cells. There are many tests,  
19 this is just a representative list.

20 We verified the ability to handle uranium  
21 and produce target solution via the FERC performance  
22 of target solution preparation. We'll be testing and  
23 balancing process vessel vent system flow rates to  
24 ensure adequate sweep gas flow, for action mitigation.

25 We'll be verifying the operation of that

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1 transfer system's ability to move target solution  
2 between storage locations. We will ensure the  
3 functionality of the tritium purification system. And  
4 also test the ability of the standby generator to  
5 automatically start and take on load. Next slide.

6 MEMBER PETTI: This is Dave. I had a  
7 question, go back. I understand, you know, at some  
8 point you'll actually, you know, use uranium and  
9 tritium.

10 But will you do tests before that with  
11 just the sulfuric acid or watered down, you know,  
12 without the radioactive material going in first to,  
13 you know, to sort of SO test without, you know,  
14 jumping straight to the radioactive material?

15 MR. DRURY: Absolutely, yeah, as much as  
16 possible.

17 MEMBER PETTI: All right.

18 MR. DRURY: We are currently doing much of  
19 what's in that first bullet point with depleted  
20 uranium in a -- in a R&D facility. The verification  
21 of the vacuum transfer system's ability to transfer.  
22 The plan is to do that entirely with water throughout  
23 the entire facility or at least as much as possible.

24 And the ability of the tritium  
25 purification system to function, that is planned to be

1 tested with protium and deuterium prior to ever  
2 involving tritium.

3 MEMBER PETTI: Great, great. And I would  
4 assume the same is true of the -- the actual  
5 accelerator stuff, that you guys have done testing, so  
6 you kind of know how it should work before it's  
7 actually in the facility.

8 MR. DRURY: Yeah, I'll get to that in a  
9 little bit. But yes, absolutely, we've run very  
10 similar accelerators. We're running the exact same  
11 model of accelerator right now with deuterium, and do  
12 deuterium. So there's been extensive testing on the  
13 accelerators without much of the risk of radioactive  
14 materials.

15 MEMBER PETTI: Okay, great, thanks.

16 MR. DRURY: So other facility tests are  
17 done to verify design parameters. One thing we'll be  
18 doing throughout the facility is, a little jumping  
19 ahead to use of radioactive materials, we'll be doing  
20 direct dose measurements throughout the facility and  
21 comparing them to our chilling calculations.

22 We will also be testing the operability of  
23 the uninterruptable power supply system. And testing  
24 all the I&C systems, both safety-related and non-  
25 safety-related control systems.



1           Moving into each individual irradiation  
2           unit, all these tests will be done for each unit, so  
3           eight times on at least -- at least eight times on  
4           these. We'll be verifying filling and drain rates  
5           conform to design specifications.

6           I've already touched on that next bullet  
7           point. The driver is extensively tested for leakage  
8           operability, stability, and yield, both what we've  
9           already tested in an R&D environment. Also in the  
10          facility, it will be tested with deuterium and do  
11          deuterium prior to introduction to tritium.

12          The -- offgas system will be tested to  
13          determine the amount of water it holds up, leak  
14          tightness, sweep gas flow rates, and its iodine  
15          removal capabilities. The primary close loop to the  
16          cooling system will be tested to make that it can  
17          automatically maintain a temperature, tested for flow  
18          characteristics. And its integrity will be  
19          periodically tested via sampling for radioisotopes to  
20          indicate leakage between the TSV and the PCLS. Next  
21          slide.

22          We'll be testing a variety of nuclear  
23          physics parameters as well. One of the first and key  
24          parameters is determining through measurements what  
25          the optimum concentration of solution is. We have

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1 calculations that say what it should be and it will be  
2 very close.

3 But we will start by filling the TSV with  
4 a solution below what we expect to be optimum  
5 concentration and fill it multiple times, leading to  
6 a concentration above the expected optimum  
7 concentration, and interpolate between the results to  
8 find a measured optimum concentration.

9 Once that is found, either with data from  
10 finding the optimum concentration or additional fills  
11 with greater-than-optimum concentration solution, we  
12 will create a curve of critical height versus  
13 concentration, which has also been calculated, so we  
14 can make more comparisons calculated and measured  
15 values.

16 And with the data gathered in these first  
17 two tests of optimum concentration and critical  
18 height, we'll be able to determine our calculational  
19 bias both in terms of uranium concentration and in  
20 terms of reactivity.

21 MEMBER MARCH-LEUBA: Hey, this is Jose --

22 MEMBER PETTI: Go ahead, Jose.

23 MEMBER MARCH-LEUBA: Yeah, do you guys --  
24 have you guys have draft of procedures or draft of  
25 plans for these tests, or is this just requirements?

1 Because what I'm thinking, this is not going to take  
2 a couple of hours, this is going to take a couple of  
3 months.

4 MR. DRURY: Yes, I think we've scheduled  
5 about two to three months for all this work. From at  
6 least the hot commissioning portion I believe is about  
7 two to three months. And we do have draft procedures  
8 for the top level bullet point of these three, plus  
9 about another 15 or so IU-specific procedures and a  
10 few other procedures throughout the plant.

11 MEMBER MARCH-LEUBA: And do they know this  
12 test, you will never reach criticality, you will  
13 always stay subcritical? Because --

14 MR. DRURY: Correct.

15 MEMBER MARCH-LEUBA: The nominal  
16 condition, I don't remember if the number is  
17 proprietary, is pretty close to k effective 1. So  
18 when you go 5% above optimal, you might be above 1.  
19 What happens then? You don't fill the time to the  
20 nominal level?

21 MR. DRURY: No, the -- these fills are  
22 stopped once we are a -- I'm choosing my words  
23 carefully because it's an open session. But we --  
24 whenever we fill the TSV, we are constantly estimating  
25 what critical is through an extrapolation of the last

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1 two count rates. And in all cases, we always stop at  
2 the same percentage below critical in terms of volume.

3 So even when we do increase the  
4 concentration above what is optimum, that just reduces  
5 the volume of solution in the TSV.

6 MEMBER MARCH-LEUBA: Okay.

7 MEMBER PETTI: So this Dave, I had a  
8 question. I'm assuming you're going to do these  
9 curves for each radiation unit because there's -- may  
10 be small changes in volumes, you know, given  
11 tolerances on the geometries and the like, so that  
12 they could be difference from one TSV to another TSV.

13 MR. DRURY: Yes, I think it's understood  
14 that maybe as data is gathered, as you can see in the  
15 second open bullet point, I say to be filled four  
16 times. Maybe as time goes on, that becomes only three  
17 as we get a better idea of where we should start.

18 But at least for the first one and the  
19 second one probably, we'll start quite a bit below  
20 what we would consider it to be optimum. Or what  
21 calculations we chose to be optimum.

22 Yeah, there is some manufacturing  
23 tolerances on each TSV, and I wouldn't expect each one  
24 to have the exact same concentration within our  
25 ability to measure concentration.

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1 MEMBER BROWN: You done, Dave?

2 MEMBER PETTI: Yes.

3 MEMBER BROWN: Yeah, it's Charlie Brown.  
4 Interesting as you went through all the slides and  
5 everything else, you -- and all the testing that you  
6 plan on doing, curiously you left out the ESFAS and  
7 TRPS. There are a lot of things that are going to  
8 trigger those particular systems in terms of a  
9 shutdown, either facility-wise or IU-wise.

10 And yet there's no mention of a test of  
11 how that's going to be tested to ensure that all the  
12 various parameters, etc., will result in the  
13 satisfactory shutdown if necessary automatically.

14 It's just a curious leave-out that it's  
15 not even mentioned in your testing program, neither  
16 one of the systems. And those are the overall  
17 protection systems for the overall facility and the  
18 IUs.

19 MR. DRURY: I said on slides 5 and 6 that  
20 these are just a representative sampling of facility  
21 test. That there's a lot more to our facility than  
22 can be put on just a couple of slides. I was hoping  
23 to capture that in that last bullet point, a  
24 functionality of instrumentation, both safety-related  
25 and non-safety, is tested.

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1           Yeah, it's understood that there'll be  
2 many days to weeks of testing every input and output  
3 and actuation to both ESFAS and TRPS.

4           MEMBER BROWN: The reason I asked the  
5 question was because if you look at what the TRPS and  
6 the ESFAS are supposed to respond to, those are, you  
7 know, they're not all that easy to generate how you  
8 generate the inputs that result in that, the  
9 simulation of those. That just seemed to a bigger --  
10 a larger scale test.

11           I understand testing on a representative  
12 sample. It's still just it was an explanation of how  
13 you were going to go about making sure that the  
14 overall safety system tests were actually conducted  
15 and worked, like they were. It just seemed to be a  
16 loose end. That's just my observation.

17           I presume the staff will make sure  
18 something's going on with those, other than just the  
19 slides here. I'll ask them the same question, or they  
20 can answer it if they know what it's going to be.

21           MR. BALAZIK: Well this is Mike Balazik,  
22 NRC staff. I will add that, you know, even though we  
23 haven't presented the tech specs with ACRS at this  
24 point, you know, the ESFAS and TRPS do have  
25 surveillance requirements prior to being considered

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1 operable. So that's one thing we can point to now.

2 MEMBER BROWN: Okay. It just seems to me  
3 these are -- if you look at all the various systems  
4 that are installed, there's all the operational, how  
5 do you produce the stuff, and then there's these two  
6 top-level systems which are for the overall safety of  
7 the facility, as well as the performance of the  
8 irradiation unit.

9 So it just (audio interference.) test is  
10 one thing but making sure they're operational and  
11 you've got, kind of a qualifying that they actually  
12 work based on inputs seems to me to be something that  
13 ought to be laid on the table, in terms of a little  
14 bit more attention to the detail in how that was done.

15 The surveillance testing is not  
16 necessarily -- it's almost like an operational set of  
17 testing before the facility can go into operation,  
18 after they've done all the other operating system  
19 tests.

20 Just an observation based on about several  
21 hundred test programs I've participated in for  
22 shipboard systems, and submarine systems. That's just  
23 an observation I'm just giving you.

24 MR. BALAZIK: No, I understand the  
25 observation, I appreciate it, Charlie.

1 MR. DRURY: Thank you for the comment.  
2 Jeff, if you could move to slide nine, it's the next  
3 slide.

4 So after we've done the other irradiation  
5 unit tests from that previous slide we'll be looking  
6 at through measurements determining a few reactivity  
7 coefficients, including the worth of PCLS somehow  
8 draining, the worth of the TOGS holdup -- the water  
9 holdup within TOGS, temperature coefficients  
10 reactivity, and also the void coefficient reactivity.

11 MEMBER MARCH-LEUBA: Can I ask a few  
12 questions? You said PCLS reactivity worth is draining  
13 it or changing the temperature, or both?

14 (Simultaneous speaking.)

15 MR. DRURY: We will be changing the  
16 temperature while we find the temperature reactivity  
17 coefficient --

18 MEMBER MARCH-LEUBA: The temperature of  
19 PCLS without affecting the temperature of the TSV,  
20 which is difficulty to do, but, I mean, what do you  
21 mean by PCLS reactivity?

22 MR. DRURY: The worth of the water within  
23 PCLS existing or not.

24 MEMBER MARCH-LEUBA: So you will drain the  
25 PCLS and see how the reactivity changes?



1 MR. DRURY: Yes.

2 MEMBER MARCH-LEUBA: And you will measure  
3 reactivity by filling the tank and reaching the  
4 critical height, and see -- basically you will drain  
5 the PCLS and find out what the critical height is by  
6 measurement, and that will be your reactivity worth?

7 Because I don't know how you measure  
8 reactivity, very difficult to do.

9 MR. DRURY: We will measure -- we will  
10 fill the TSV with solution, with PCLS drained, measure  
11 the count rate on the startup -- on the source range  
12 detectors, and then fill PCLS. And a comparison of  
13 those two count rates will give us a reactivity worth  
14 of PCLS.

15 MEMBER MARCH-LEUBA: You will have the  
16 detectors calibrated by then?

17 MR. DRURY: It's a relative count rate  
18 between the two. It's a source range so it's counting  
19 pulses, the relative pulse wouldn't need to be  
20 calibrated.

21 MEMBER MARCH-LEUBA: So reactivity is the  
22 ratio of power -- yeah, I agree with that.

23 Okay, the TOGS holdup, are you planning to  
24 do different concentrations of solution and fill it up  
25 again, or run it at full power for however long it

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1 takes the TOGS reach equilibrium? How do you plan to  
2 do that?

3 MR. DRURY: The plan is to run at two  
4 different concentrations, keeping the uranium mass the  
5 same. So you'd have different concentrations,  
6 different volumes that would be representative of --

7 MEMBER MARCH-LEUBA: Of losing water,  
8 holding water in the TOGS.

9 MR. DRURY: Yes.

10 MEMBER MARCH-LEUBA: Yeah, that's probably  
11 good.

12 And now, void reactivity, I saved the best  
13 for last. Measuring void is really hard, especially  
14 where the TSV has a 3D void distribution radial axial.  
15 Have you given any thought of how you're going to do  
16 that? Or is you going to do a power coefficient,  
17 you're going to change the power level?

18 MR. DRURY: We have a good idea now how to  
19 get a qualitative measurement of void, but I don't  
20 think we have a great handle on how much void is in a  
21 TSV at power. So the -- in the next few months or  
22 year before we do this, hopefully we can come up with  
23 -- perhaps we can come up with a more quantitative way  
24 of doing it.

25 But the qualitative way is that, as we

1 startup we expect hydrogen and oxygen not to release  
2 immediately and then, at first, hydrogen will bubble  
3 out and then followed by oxygen. So at, least  
4 qualitatively, we want to say that void coefficient is  
5 negative, and I would expect to be able to do that  
6 just by seeing two close two-step change drops in  
7 response from the wide and power range detectors.

8 MEMBER MARCH-LEUBA: So you're not really  
9 interested in the absolute magnitude of the  
10 coefficient but the fact that this negative is good  
11 enough for you?

12 MR. DRURY: For right now, yeah, strong  
13 and negative is good enough. If we can find a way to  
14 actually quantify it -- like you said, it might be  
15 very difficult or impossible -- that would be great.  
16 And it would be added to the plan -- strong and  
17 negative is good.

18 MEMBER MARCH-LEUBA: Yeah, the problem is  
19 that the void is a 3D environment, I mean, it's not to  
20 scale. The void at the bottom will be higher and  
21 there will be a radial distribution on the whole TSV,  
22 it will follow the flux, right?

23 So, yeah, I'm hoping you have final --  
24 because the idea here is that you are going to verify  
25 that whichever void reactivity coefficient,

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1 quote/unquote, you use for your safety analysis, you  
2 have either -- you have something safer than what you  
3 use. And I just don't see how we're to do that -- I  
4 can see how you can do a power reactivity coefficient,  
5 total power, that's relatively easy to do --

6 MS. RADEL: Jose, this is Tracy. You  
7 know, we have the ability to measure the volume of  
8 solution and tell the -- be able to measure the total  
9 void in the solution. But you're right, it's  
10 distributed and, you know, depending on bubble size  
11 and speed in the solution, and then, you know, power  
12 distribution aspects, you know, we will be comparing  
13 that total void to the models that we have and  
14 adjusting our models on the bubble size and speed, and  
15 those parameters to match as close as possible as we  
16 can to the unit as somewhat of a bias and confirmation  
17 of what we're seeing in all of the modeling. But, you  
18 know, we will not be able to measure void in each  
19 individual region within the TSV.

20 MEMBER MARCH-LEUBA: So let me ask you, do  
21 you have an actual level measurement? Not collapse  
22 level, but where the froth level is, where the actual  
23 boundary between the water and the gas on top is?

24 MS. RADEL: So the level measurement is  
25 done in a standpipe, kind of on the side of the TSV --

1 (Simultaneous speaking.)

2 MEMBER MARCH-LEUBA: Yeah, that's collapse  
3 level, that doesn't give you the void. You will need  
4 some kind of -- I mean, some kind of level measurement  
5 that looks for the boundary between the liquid and the  
6 gas, and that will elevate as you get more voids.

7 Okay, that's not relevant, that would be  
8 a nice way to measure the void. But the positive  
9 thing you have is that you don't have any burn up or,  
10 in BWRs, your power distribution changes daily.

11 In SHINE you always have the same power  
12 distribution, there is no burn up. So day one of the  
13 cycle have the same flux distribution in the TSV as  
14 day seven or day 30, so you only have one void  
15 distribution always, and whichever it is, it is. As  
16 long as you can measure a reactivity coefficient for  
17 the one and only void distribution you have, that will  
18 be sufficient, I think. But anyway, I'm diverging  
19 here.

20 So I'm just saying, this is a difficult  
21 problem. We need to -- you need to figure out what is  
22 it that you need and don't do more than you need to  
23 demonstrate that you are within the safety analysis  
24 assumptions. Okay. All better now.

25 MR. DRURY: Next slide.

1           And this is our final slide, one of the  
2           last things to do during commissioning is the initial  
3           calibration of the wide and power range neutron flux,  
4           we will do a run where power is limited by limiting  
5           neutron production from the NDAS, from the neutron  
6           driver assembly system.

7           We will do a few hour run, somewhere in  
8           the four to 10 hour run, at approximately 10 percent  
9           power. From that the detectors will be calibrated the  
10          way they were described yesterday during the INC  
11          portion of this meeting, using a isotopic method, and  
12          then extrapolated to 100 percent power.

13          If it looks like we need to do another run  
14          before 100 percent power, we can do an intermediate  
15          power and then followed by another few hour run at  
16          full power to calibrate at the power conditions.

17          Then we will do a few more at higher  
18          concentrations and lower fill heights to investigate  
19          if there's any sensitivity to the detector calibration  
20          factors with solution geometry, the calculations  
21          currently show that there probably is a small  
22          sensitivity to that and we would like to confirm that.

23          And that's all I've got for startup  
24          testing.

25          MEMBER SUNSERI: This is Matt, I guess --

1 I'm going to make just a comment here, I suppose. But  
2 the title of this section is StartUp Plan, there  
3 really is not a startup plan has been presented.  
4 There's a list of activities here, some system level  
5 test, a real startup plan would have a definition of  
6 a controlled, systematic and progressive approach from  
7 the construction to full power operation.

8 It would start with prerequisite testing,  
9 such as wiring continuity checks, system flushes,  
10 instrument calibrations. Would proceed to system and  
11 component level testing, including performance tests  
12 and whatever technical specifications the plant  
13 conditions would allow, it would specify what  
14 conditions you want to test in pre-irradiation, post-  
15 irradiation, how the systems are (audio interference.)  
16 be, and ultimately some kind of integrated test to  
17 show all the systems working together work together as  
18 you intend.

19 The purpose of that would be, as you  
20 described earlier, would be to validate the  
21 construction against the design, validate the design  
22 itself. It's also an opportunity to exercise your  
23 operational procedures, which are newly developed and  
24 haven't been operated. It would identify some things  
25 that maybe your design was weak on, or you had design

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1 deficiencies. And you could do this prior to either,  
2 irradiating material or introducing radioactive  
3 material to the system.

4 So, you know, a lot of the questions you  
5 got today were simply because we don't see those  
6 connections, and it's hard to tell whether or not  
7 those systems that are listed here and in the SAR are,  
8 you know, comprehensive.

9 And so I don't -- I think the staff is  
10 going to conclude that there's reasonable assurance,  
11 I probably could convince myself the same thing but  
12 without having to see the documented full-scope plan,  
13 it's really kind of hard to tell. I'll just leave it  
14 at that.

15 CHAIRMAN BALLINGER: Yeah. This is Ron  
16 Ballinger, I sort of had the same opinion since I've  
17 been involved in at least two startups like this. But  
18 I think it's all in there, it's just not organized in  
19 a way that I'm used to seeing it. What do you think,  
20 Matt?

21 MEMBER SUNSERI: Well certainly the SHINE  
22 facility isn't of the magnitude of a commercial power  
23 reactor. Reg Guide 1.68 describes the, you know,  
24 initial startup program for a reactor of that type.  
25 It would be a good example to look at it, at the

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1 things that you would want to, you know, ensure that  
2 you're covered, on a smaller scale, as applicable to  
3 the SHINE facility.

4 But, I mean, you know, I suppose it's a  
5 given that whoever's building the place is going to do  
6 construction-level tests, they're going to flush the  
7 systems, they're going to do wiring continuity checks  
8 -- but without it being documented in a, you know --  
9 what I'll say -- or prescribed, maybe not documented  
10 but prescribed in a plan, it's just hard to tell that  
11 all the pieces are going to add up to the total at the  
12 end.

13 MS. KOLB: This is Catherine Kolb, the  
14 examples of testing that you gave there, so we don't  
15 have the kind of plan that's, you know, lays out every  
16 test that we're going to do -- and I admit that maybe  
17 we struggled a little bit on the slides to convey the  
18 scope of the startup testing, and the commissioning.

19 But in our integrated schedule we have all  
20 the things that we mentioned, we have, you know,  
21 checking the continuity of wiring, system flushes, you  
22 know, performing all of the technical specification  
23 surveillances, individual component tests that then go  
24 into integrated system tests prior to the introduction  
25 of radioactive material. And then this series of

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1 testing for -- nuclear physics testing and other  
2 things that we discussed in a little bit more detail.

3 We also have in our integrated schedule  
4 (audio interference.) line items to go and verify and  
5 validate all of the individual operating procedures  
6 that Chris mentioned earlier, so, yeah, we do lack a  
7 single document that lists all of these together.  
8 We're mostly relying on our project schedule to list  
9 out and coordinate all of the activities that we're  
10 going to do in order to ensure the facility will be  
11 operational.

12 MEMBER SUNSERI: Your required startup  
13 report would be halfway written if you had such a plan  
14 in place, because then all you would have to do is  
15 fill in the results when you get them done, so.

16 MS. KOLB: That is an excellent comment,  
17 thank you for that.

18 MEMBER PETTI: I had a question. I didn't  
19 hear a lot about -- because, again, it's not  
20 necessarily safety related, but the whole recovery of  
21 the moly-99, etcetera, you know, you've got eight  
22 units feeding, what is it, more than one tank. But  
23 there's, you know -- I suppose it's hard to do much in  
24 terms of quantifying yield, carryover issues, process  
25 variability until you get into it. Unless, you know,

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1 someone's able to come up with a way to kind of do  
2 some of that with non-radioactive Moly, you know, and  
3 just do some other chemical analysis.

4 Are you guys doing, you know, thinking  
5 about anything on that end? I mean, are you going to,  
6 you know, gather data and do statistical process  
7 control on some of this stuff so that you, you know,  
8 you know where you sort of should be when something  
9 looks wrong? That sort of stuff.

10 Again, it's not a safety issue, it's more  
11 of a, you know, making sure you're meeting whatever  
12 the production targets you have.

13 MS. KOLB: Yeah, so this is Catherine  
14 again, we don't have plans to do statistical analysis  
15 of that type in this initial facility startup, you  
16 know, we may choose to do that as we, you know, run  
17 our first year or two of operation.

18 But your comment about, you know, doing  
19 some testing with cold materials, we have done that on  
20 a little bit of a scale. You could use natural moly  
21 and do some of the processes with non-irradiated  
22 material and get, you know, some amount of information  
23 from that, including, you know, varying different  
24 parameters and seeing the results. It's not quite the  
25 same as moly-99 but we do have a setup, using some

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1 cold moly, that we're working on.

2 MEMBER PETTI: You know, just a point  
3 that, if you, you know, are going to go there  
4 eventually it just means, collect as much data as you  
5 can now, even on things that you might not think are  
6 important but could end up being important when one  
7 looks at it, you know, as a process, if you will.  
8 That data could be quite helpful in informing your  
9 decision on how you really want to look at things, you  
10 know, down the line.

11 MS. KOLB: Yes, that makes sense. Thank  
12 you.

13 CHAIRMAN BALLINGER: Additional questions  
14 from members or consultants?

15 (No audible response.)

16 CHAIRMAN BALLINGER: Well thank you again,  
17 let's switch over to the staff, please.

18 MR. BALAZIK: All right. Good afternoon,  
19 my name's Mike Balazik, I'm the project manager in the  
20 Office of Nuclear Reactor Regulation in the Non-Power  
21 Production and Utilization Facility Licensing branch,  
22 and I'll be presenting the NRC staff review of SHINE's  
23 startup plan, as described in FSAR chapter 12, section  
24 11. Next slide, please.

25 Okay, big picture here, 5034 describes the

1 information required to be in a safety analysis  
2 report. Section B6, item three, talks about plans for  
3 pre-operational testing and initial operations, a  
4 couple other regulations that apply, and these, you  
5 know, provide reasonable assurance that the activities  
6 authorized by the operating license can be conducted  
7 without endangering the health and safety of the  
8 public, and that the activities will be conducted in  
9 compliance with the regulation and not be inimical to  
10 the common defense and security.

11 So 5040 and 5057 are some of the standard  
12 regulations we've been applying throughout the review.  
13 The 5034-B6 is specifically tied to the startup plan.  
14 Next slide, please.

15 All right, so guidance, same guidance that  
16 you've seen in some of the other reviews, NUREG 1537  
17 part one and part two, and also the interim staff  
18 guidance for licensing radioisotope production  
19 facilities, and aqueous homogeneous reactors. Next  
20 slide, please.

21 Okay, I just wanted to first talk about  
22 the summary of the application in section 12.11, SHINE  
23 did identify at a high level, the tested measurements  
24 to verify safety-significant facility parameters for  
25 handling special nuclear material, and also validating

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1 operating characteristics of the facility.

2 While we didn't receive acceptance  
3 criteria within the startup plan, you know, the NRC  
4 staff acknowledges that specific test plans will  
5 contain this acceptance criteria which will be  
6 developed by the design information in the FSAR.

7 Also in the tech specs, SHINE is required  
8 to submit the startup report which contains all of the  
9 startup information, this is required by tech spec  
10 5.84 which requires, like I said, the submission of  
11 the information within six months after the completion  
12 of the startup activities.

13 Okay. So continuing on with the summary  
14 of the application, SHINE identified, again, at a high  
15 level, system testing for the facility and the  
16 individual IUs, they identified calibrations of  
17 equipment, system flow, fill, and drain rate, and leak  
18 rates to verify boundary integrity.

19 They also identified measuring certain  
20 nuclear parameters, such as uranium concentration,  
21 critical height, temperature and void coefficients,  
22 the TSV off-gas system and the primary closed loop  
23 cooling system reactivity worth, determining a  
24 neutronic bias, and also determining flux  
25 distribution, and also to be looking at radiation

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1 measurements outside the biological shield.

2 One thing I do want to add here is that,  
3 I did go back and look at some of the startup testing  
4 programs we've reviewed in the past, specifically I  
5 looked at some of the HEU to LEU conversions that we  
6 did for the TRIGA reactors. For those SARs, the  
7 licensees did submit a startup plan which was at a  
8 high level.

9 I'll say that some of them did contain  
10 some acceptance criteria but it was, again, kind of  
11 qualitative. For example, I saw in there where, you  
12 know, they wanted to verify the temperature  
13 coefficient of reactivity was negative, or that they  
14 met the shutdown margin in their tech specs, or that  
15 their pulsing versus fuel temperature has a linear  
16 response.

17 But I will say that, with those startup  
18 reports that were submitted -- this was probably back  
19 in the mid to late 2000s -- I'll say that SHINE's  
20 startup plan is on par with the information that was  
21 provided in those startup plans --

22 MEMBER SUNSERI: This is Matt again,  
23 wouldn't you agree, though, that SHINE is  
24 significantly more sophisticated than a TRIGA reactor?

25 MR. BALAZIK: Yes, sir. I do agree with

1       that.

2                   We've had quite a lot of operational  
3       experience with the TRIGA reactor, SHINE is a first of  
4       a kind, and, you know, at this (audio interference.)  
5       we'll have to move some of these activities to the  
6       oversights out of the house and inspect the testing  
7       that's going on with SHINE. I'll actually talk about  
8       that on the next slide here.

9                   MEMBER SUNSERI: Okay.

10                  MR. BALAZIK: So just evaluations and  
11       conclusions, you know, SHINE has identified plans to  
12       validate safety-significant parameters. They do plan  
13       on developing acceptance criteria based on FSAR design  
14       information to support their startup test procedures,  
15       they'll submit the information within six months of  
16       completion of startup activities.

17                  And I'll conclude that the implementation  
18       of this startup plan -- again, it's a high level plan,  
19       I kind of call it a plan for, to support the test  
20       procedure, it provides reasonable assurance that the  
21       facility can operate as described in the FSAR. And I  
22       also want to add that the NRC will conduct inspection  
23       activities to confirm the readiness of the startup  
24       test program. Next slide, please.

25                  So I do want to say that the Licensing



1 branch and the RTR Oversight branch are working  
2 closely together, we are developing a SHINE facility  
3 specific inspection plan that will include the SHINE  
4 startup test program. During those inspections we can  
5 verify the acceptance criteria for all the different  
6 tests and parameter measurements that SHINE discussed  
7 earlier.

8 Our main procedure that we plan on using  
9 is 69002, which is inspections of operational  
10 readiness during construction of non-power production  
11 and utilization facilities. Within that inspection  
12 procedure it talks about using other existing  
13 operational inspection procedures as guidance.

14 You know, this inspection procedure is  
15 technology-neutral, it is written at a high level but  
16 one inspection procedure that we can use information  
17 from is inspection procedure 72401, this talks about  
18 part 52, Inspection of StartUp Test Programs.

19 Within that procedure it talks about, you  
20 know, reviewing the acceptance criteria, you know, if  
21 the acceptance criteria wasn't met, you know, what  
22 were the corrective actions that the licensee  
23 implemented. It talks about lots of other inspection  
24 guidance related to startup activities.

25 That is my presentation, are there any

1 questions that I can answer?

2 MEMBER SUNSERI: Well this is Matt again,  
3 and I'm just one member as you know, and don't speak  
4 for the ACRS as a whole on this thing. I would give  
5 a lot of weight to this inspection program for  
6 validating the rigorousness -- rigor? Whatever -- the  
7 strength of their startup test program.

8 Because, as you mentioned, this is a first  
9 of a kind facility, it's got a unique operating  
10 requirement, as that it's going to be operating close  
11 to but not at critical. So, you know, you'd want to  
12 make sure that the plant is going to operate that way,  
13 and the only way -- the best way to do that is during  
14 the test program, to make sure that its been  
15 methodically tested, staged, incrementally progressed  
16 to the point of which you assured that it's going to  
17 operate below critical and not at or above, which is  
18 a safety limit, I think, for the unit, so.

19 The test program's very important and it  
20 just doesn't seem like it's gotten the attention that  
21 I would've expected it should've gotten for a  
22 licensing review. That's my opinion.

23 MR. BALAZIK: Yes, sir. No, one thing we  
24 have identified when we're -- in developing these  
25 inspection program is that we're going to need a lot

1 more technical expertise to support the inspections.  
2 I mean, for a TRIGA reactor you can have one person  
3 knowledgeable about the design of that facility, but  
4 for SHINE, from a MC&A, from a criticality standpoint,  
5 you know, we're going to need those experts, those  
6 additional experts to support the inspections of this  
7 facility.

8 And I'll also add that we have an ongoing  
9 construction inspection program, they're verifying the  
10 as-built facility, as-built now. It meets the  
11 information that's in the FSAR, so we're doing that  
12 and that's one place where we can also look at the  
13 digital INC that Mr. Brown was mentioning earlier.

14 MEMBER PETTI: Mike, could you -- this is  
15 Dave, could just go back a slide?

16 MR. BALAZIK: Yep, sure.

17 MEMBER PETTI: Yeah, so this last bullet,  
18 that's a hold point, they can't go forward until you  
19 give them an authorization or is it just something  
20 done in parallel?

21 MR. BALAZIK: Can you clarify what you  
22 mean by hold point?

23 MEMBER PETTI: They can't start a startup  
24 program until you do the inspection activities and --

25 MR. BALAZIK: Yes.

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1 MEMBER PETTI: Okay.

2 MR. BALAZIK: The pre-operational  
3 readiness inspection supports the 5057 finding that  
4 the facility is substantially complete.

5 MEMBER PETTI: Okay. I just, you know --  
6 I mean, I want to echo Matt's comments. The DOE  
7 facility is -- the DOE complex is replete with  
8 facilities that didn't do enough pre-op work and just,  
9 you know, ended up doing it when they were, quote, in  
10 operation. And of course the availability goes to  
11 hell, I mean, all this stuff happens -- this is really  
12 important stuff, and I'm sure SHINE appreciates. When  
13 they're ready they want to really be ready, and so the  
14 more you can do here, you're just, you know, saving  
15 yourself headaches down the line.

16 MR. BALAZIK: And one thing I'd like to  
17 add is that, you know, when SHINE informs the NRC that  
18 they're ready for certain inspections, we want to get  
19 those knocked out early so that this entire, I'll say,  
20 inspection program for pre-operational readiness can  
21 be done efficiently.

22 Any other questions?

23 MEMBER SUNSERI: This is Matt, I don't  
24 have any. Thanks for listening to us.

25 MR. BALAZIK: Thank you.

1 MEMBER SUNSERI: Ron, are you there? I  
2 think that's it for us.

3 CHAIRMAN BALLINGER: Yeah. No, I -- boy  
4 oh boy, I pulled a you know what and didn't unmute.  
5 Anyway, with this concludes the last presentation, and  
6 so, absent any questions from members or consultants,  
7 we need to go out for public comment.

8 So I might would say that, if there are  
9 members of the public that would like to make a  
10 comment please unmute yourself, and state your name  
11 and make your comment.

12 (No audible response.)

13 CHAIRMAN BALLINGER: Well, not hearing  
14 any, I think there are no public comments. Now we  
15 need to have the discussion -- I think I know the  
16 answer, but we had scheduled closed sessions after  
17 this, if needed, and my question to the members is --  
18 or anybody else involved, actually -- whether you  
19 think we need a closed session?

20 MEMBER BROWN: None from me, I don't need  
21 --

22 (Simultaneous speaking.)

23 MEMBER SUNSERI: This is Matt, I don't see  
24 the need for any.

25 CHAIRMAN BALLINGER: Okay, so I'm going to

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1 conclude that we don't need a closed session. And so  
2 I would like to be the first to thank the staff and  
3 the SHINE folks for presentations, they were, to my  
4 mind, complete. And I think we got most of our  
5 questions -- or all of our questions answered.

6 So are there any final -- excuse me, a  
7 train is about to go by. No, you didn't hear it --  
8 are there any final questions from members or  
9 consultants?

10 (No audible response.)

11 CHAIRMAN BALLINGER: Okay. And once again  
12 I'd like to thank the staff and the SHINE folks for  
13 their presentations. And I think we are finished for  
14 the day, so thanks again.

15 (Whereupon, the above-entitled matter went  
16 off the record at 2:45 p.m.)  
17  
18  
19  
20  
21  
22  
23  
24  
25



# Operator Training and Requalification

BRENT WALLER, TRAINING MANAGER

# Initial Training Program

- Candidate Selection
  - SHINE follows the guidance of ANSI/ANS-15.4-2016, “Selection And Training Of Personnel For Research Reactors,” for the selection of licensed operator candidates
  - Medical screening are conduction per the guidance of ANSI/ANS-15.4-2016
- Candidate Training
  - Combination of classroom, on-the-job, and computer-based training
  - Phases:
    - Fundamentals
    - Radiation Protection and Administrative Requirements
    - Systems
    - Plant Evolutions (including normal, abnormal, and emergency procedures)
    - Exam Preparation
    - Supervisory Training



# Initial Training Program

- Examinations
  - Written examination passing criteria is 70%
  - Remediation conducted and reexaminations administered for scores < 70%
  - On-the-job evaluations used for performance tasks
  - Oral exams used as-needed
- Program Content
  - 10 CFR Part 55 requirements, as applicable
  - ANSI/ANS-15.4-2016 guidance
  - Additional topics identified in Chapter 12.10 of the FSAR
  - Additional topics as determined by a systematic approach to training

# Initial Training Program

- Application
  - NRC Form 398 used for application
  - NRC Form 396 used for medical
  - Internal SHINE review of candidates conducted prior to sending to an NRC exam
- Program Review
  - Performance evaluation after training as part of the systematic approach to training process
  - Assessed by the Review and Audit Committee every three years

# Continuing Training Program

- Starts within three months of receiving operator licenses
- Conforms to requirements of 10 CFR 55.59(c) and follows guidance of ANSI/ANS-15.4-2016
- Biennial Requalification Cycle
  - 24 months long
  - Divided into two, 12-month long annual cycles
  - The next cycle starts immediately after the previous
- Medical certifications conducted per the guidance of ANSI/ANS-15.4-2016
- Changes in operator license status per 10 CFR 50.74 communicated to NRC within 30 days

# Continuing Training Program

Continuing Training Program Requirements	Periodicity
Facility Design, Procedure, and License Changes	As Applicable
Training Lectures	Quarterly
Documentation of Proficiency	Quarterly
Abnormal and Emergency Procedure Reviews	Once per Annual Cycle
Reactivity Manipulations Completion	Once per Annual Cycle
Operating Test	Once per Annual Cycle
Written Exam	Once per Biennial Cycle
Medical Exam	Once every 2 years

# Continuing Training Program

- Program Content
  - 10 CFR Part 55 requirements, as applicable
  - Facility modifications
  - Procedure changes
  - Topics as identified by the systematic approach to training
  - Relevant industry operating experience
  - Identified operator weaknesses
- Program Review
  - Assessments per the systematic approach to training
  - Assessed by the Review and Audit Committee every 24 months

# **Advisory Committee on Reactor Safeguards**

## **SHINE Medical Technologies, LLC Operating License Application**

### **Chapter 12.10 - Operator Training and Requalification**

**Travis Tate  
Branch Chief  
Office of Nuclear Reactor Regulation**

**July 20, 2022**

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# Operator Requalification

- Operator Requalification is intended to ensure that the facility will be operated by competent operators
- SHINE will be issued a Part 50 facility operating license
- Paragraph (b)(8) of 10 CFR 50.34 applies
- Applicant is required to submit a description and plans for implementation of an operator requalification program

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# Regulatory Basis

- Regulatory Requirements
  - 10 CFR 50.34, “Contents of applications; technical information”
  - 10 CFR 50.54, “Conditions of licenses”
  - 10 CFR 55.59, “Requalification”



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# Acceptance Criteria

- Chapter 12.10, “Operator Training and Requalification,” of NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content,” (ADAMS Accession No. ML042430055)
- Chapter 12.10, “Operator Training and Requalification,” of NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria.” (ADAMS Accession No. ML042430048)

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# Review Areas and Technical Evaluation

- Requalification Program Elements
  - Requalification Schedule
  - Pre-planned Lectures
  - On-the-job Training
  - Operator Evaluations
  - Recordkeeping

---

# Requalification Program

- Requalification program is described in the SHINE Licensed Operator Continuing Training Program
- Regulations for requalification are found in 10 CFR 55.59
- SHINE licensed operator continuing training program includes:
  - Two-year (biennial) requalification program cycle
  - Pre-planned lectures based on topics related to the SHINE facility
  - On-the-job training applicable to the SHINE facility design: reactivity manipulations, facility procedures, and facility changes
  - Evaluations of licensed operators: annual operating tests, comprehensive written examinations, systematic observations, simulation of abnormal or emergency conditions, and provisions for accelerated requalification
  - Recordkeeping and retention periods for program documentation

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# Requalification Program (cont'd)

- SHINE licensed operator continuing training program also includes:
  - Definitions specific or unique to the SHINE facility
  - Additional information specific to license conditions for Part 55 licensed operators: biennial medical examinations, maintaining a license in active status, fitness for duty, changes in license operator status
  - Periodic requalification program audit

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# Evaluation Findings and Conclusions

- SHINE's licensed operator continued training program is in accordance with the applicable regulations for requalification contained in 10 CFR 55.59, meets acceptance criteria in NUREG-1537, and consistent with the guidance contained in industry standard ANSI/ANS-15.4-2016
- The licensed operator continued training program provides reasonable assurance that requalification for licensed operators and licensed senior operators will be carried out in a manner that assures knowledge, skills, and proficiency will be maintained and is sufficient for the issuance of an operating license

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# Operator Initial Training

- Operator Initial Training is intended to ensure that applicants will be prepared for licensure under 10 CFR Part 55 and the facility will be operated by competent operators
- SHINE will be issued a Part 50 facility operating license
- Section 50.120 of 10 CFR Part 50 does not apply
- Applicant committed to follow industry guidance in ANSI/ANS-15.4-2016, “Selection and Training of Personnel for Research Reactors”

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# Training Program

- Training program is described in the SHINE Licensed Operator Initial Training Program
- SHINE licensed operator initial training program includes:
  - Commitment that trainees will only operate controls under direct supervision of a licensed operator
  - Reactivity manipulation plans for licensed operator candidates
  - Plans to account for previous experience and training
  - Training program scope and topics for operators
  - Training program scope and topics for senior operators
  - Medical certification and fitness for duty
  - Licensed operator candidate selection and qualifications
  - Evaluations of licensed operator candidates
  - Periodic program review
  - Recordkeeping

---

# Evaluation Findings and Conclusions

- SHINE's licensed operator continued training program is consistent with the guidance contained in industry standard ANSI/ANS-15.4-2016





# Human Factors Engineering

KRIS RUETZ, OPERATIONS MANAGER

# Outline

- Human Factors Engineering (HFE) Overview
- HFE Design Guidelines
- HFE Design Checklist
- Alarm Hierarchy
- Equipment Labeling
- Operating Procedure Validation

# Human Factors Engineering Overview

- SHINE incorporates HFE principles into the design of the facility control room, display screens, and operator interfaces
- SHINE Operations works with SHINE Engineering to ensure human factors are considered throughout the design process
- The SHINE HFE program describes evaluating HFE as part of the following phases:
  - Initial design
  - Design implementation (confirming as-built design)
  - Future modifications
- HFE evaluations are performed using a checklist that compares design to recommended design guidelines
- HFE evaluations are maintained as records

# Human Factors Engineering Design Guidelines

- HFE design guidelines are recommendations, not requirements
- Four Categories of design guidelines:
  - Instrumentation and control (I&C) panel layout
  - Main control room layout
  - Human-System Interface (HSI) design criteria
  - Alarm system criteria
- Design guidelines are provided to vendors developing the SHINE HSIs
- Design guidelines are derived from relevant industry standards, including NUREG-0700, Revision 2, “Human-System Interface Design Review Guidelines”

# Human Factors Engineering Design Checklist

- HFE design checklists are used to compare design to the recommended design guidelines
  - Checklists are filled out by the Operations department
  - Checklists are used during initial design, after installation, and as part of equipment modifications
  - Checklists are kept as records
  - Issues identified that require corrective action are tracked via the SHINE Issues Management process (i.e., the SHINE corrective action program)

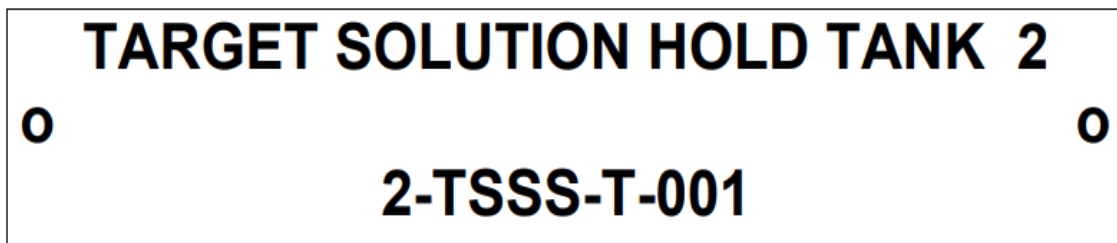
# Alarm Hierarchy

- Most facility alarms will be received in the control room via the process integrated control system (PICS)
- The PICS displays alarms on a consolidated alarm page on the control room HSIs
- “Stacklights” in the control room alert operators to current facility alarm status
  - Provides operators with high-level facility alarm status
  - Each irradiation unit (IU) has its own alarm light
  - Additional alarm light for common alarms (non-IU specific alarms)
- Categories of alarms:
  - High (red light and audible alarm)
  - Medium (yellow light)
  - Low (blue light)
  - Information (no stacklight indication, PICS alarm page only)

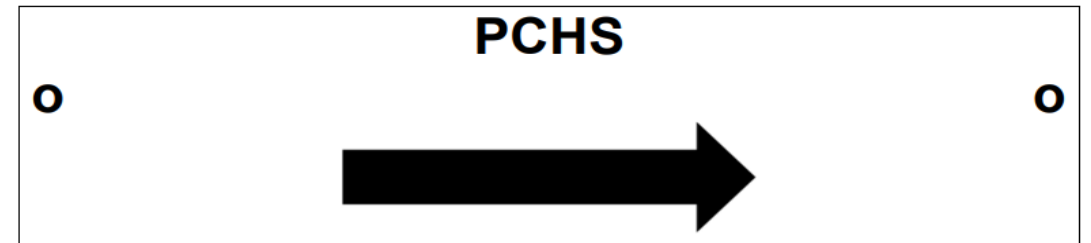


# Equipment Labeling

- Equipment and pipe labels are included within the scope of the HFE program
- Equipment labels include a descriptive name and equipment designator (unique identifier)
  - Equipment labeling includes components such as valves, pumps, and tanks
- Pipe labels include the system name and arrows showing direction of flow
- During the facility construction and commissioning process, equipment and pipe label verification is performed as part of turning over systems to Operations



*Ex. Equipment Label*



*Ex. Pipe Label*

# Operating Procedure Validation

- Operating procedures (including abnormal and emergency procedures) are validated prior to being issued for use
  - Process for procedure validation varies based on type and content of procedure
    - Most validations will consist of step-by-step facility walkthrough of procedure after related equipment has been installed
    - Alternate methods used for validation may be tabletop discussion
- Procedure validation ensures that operators can physically perform procedures and provides a diverse method of checking for necessary equipment labels



# **Advisory Committee on Reactor Safeguards**

## **SHINE Medical Technologies, LLC Operating License Application**

### **Chapter 7.4.9 - Human Factors Engineering (HFE)**

**Jesse Seymour  
HFE Technical Reviewer  
Office of Nuclear Reactor Regulation**

**July 19, 2022**

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# Human Factors Engineering

- The NRC HFE staff evaluates applications for operating licenses
- These reviews support public health and safety by verifying that the applicants' HFE programs incorporate practices and guidelines that are acceptable to the NRC staff
- The NRC staff reviewed the HFE-related portions of SHINE FSAR Chapters 3, 7, 12, and 13 to assess the sufficiency of the HFE-related design aspects and programmatic considerations for the SHINE facility

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# Regulatory Basis

- 50.34(a)(3) requires the PSAR to include PDC
  - Design Criterion 6 states “a control room is provided from which actions can be taken to operate the irradiation units safely under normal conditions and to perform required operator actions under postulated accident conditions”
- 50.34(b) requires the FSAR to include a description and analysis of SSCs and the evaluations required to show that safety functions will be accomplished
- 50.57(a)(3) requires reasonable assurance that activities authorized by operating licenses will not endanger the health and safety of the public

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# Acceptance Criteria

- NUREG-1537 and its associated ISG provide primary source of review guidance as the relevant SRP
- There are no specific HFE criteria in NUREG-1537
- Certain I&C review criteria from NUREG-1537 section 7.6 have HFE-related aspects
  - These criteria cover the following areas:
    - outputs and display devices observability
    - accessibility/understandability of important controls and displays
    - control console annunciators and alarms

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## Acceptance Criteria (continued)

- Administrative controls and HFE-related management measures supporting their reliability were evaluated using applicable criteria of the NUREG-1537 ISG
- NUREG-1520, was also consulted for general guidance regarding appropriate areas for evaluation in the review of SHINE's administrative controls
  - Procedure management
  - Procedure verification & validation
  - Training of personnel
  - Personnel qualifications

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# Regulatory Audit

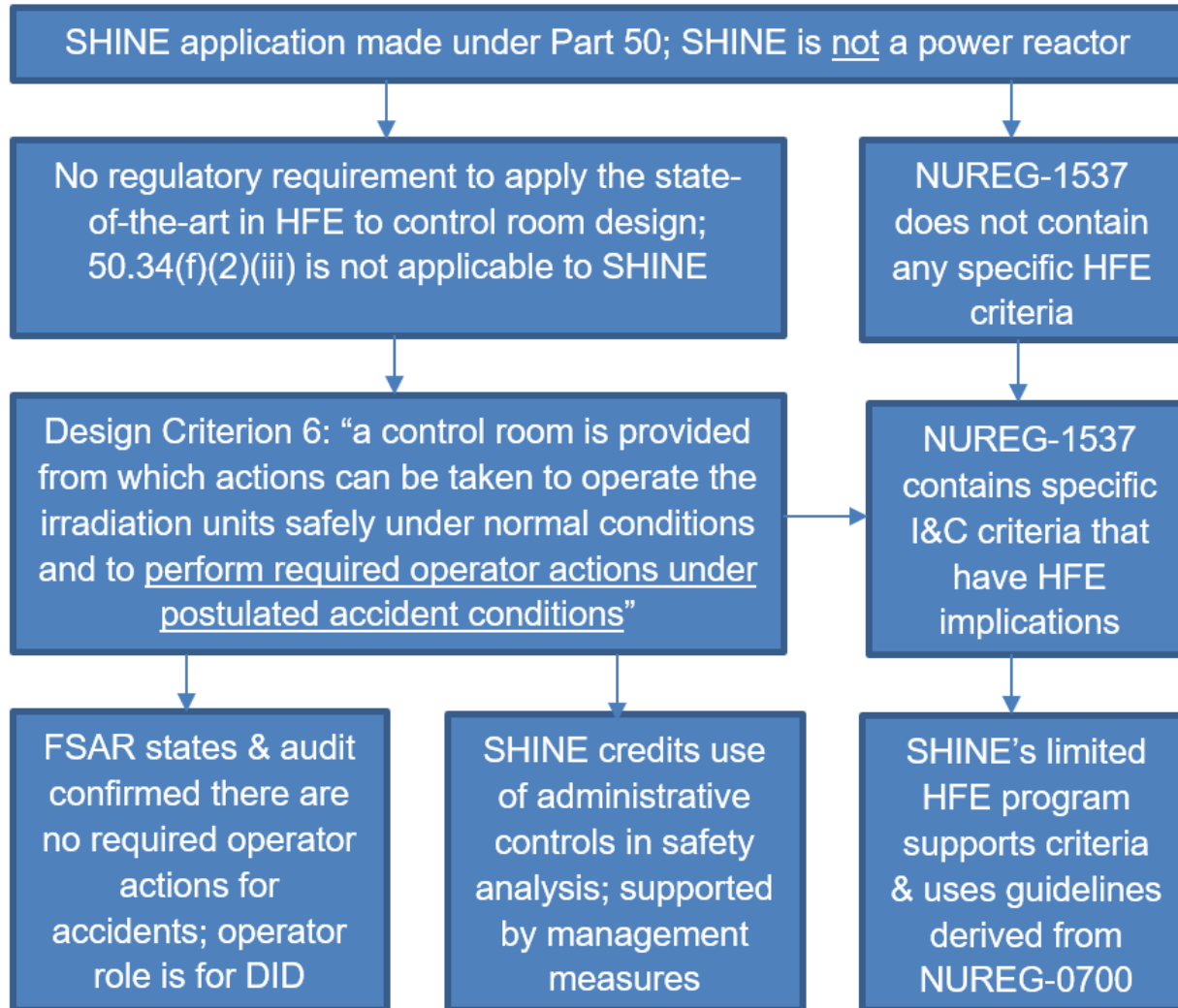
- Used to scope review and understand operator role
- General topical areas covered included:
  - HFE program & control room design
  - operator role in facility safety & DID
  - operations staffing & training programs
  - administrative controls
- Reviewed documents included:
  - SHINE's Safety Analysis Summary Report
  - HFE program, style guide, & design checklist,
  - Operations Procedure Development
  - Licensed Operator Initial & Continuing Training Programs

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## Key Insights from Audit

- Role of operators with respect to safety at the SHINE facility is associated with:
  - DID actions (i.e., manual TRPS & ESFAS)
  - Implementation of administrative controls (note: there are no post-event mitigation actions)
    - This information was applied to scope the review used to make the regulatory findings
- HFE Program establishes design guidelines and implements a checklist for verifying HFE attributes during equipment design and following equipment installation; guidelines partly based on NUREG-0700

# Overview of Review Approach & Basis





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## **Technical Evaluation: Safety Displays (NUREG-1537 Section 7.6)**

The staff evaluated whether displays showing parameters related to facility safety would be readily observable by the operator while positioned at the SHINE facility control room operator workstations and the main control board

- Focus placed on workstations for PICS and NDAS, plus main control board TRPS and ESFAS indications
- Main control board accessibility & visibility considered
- Design of control room, display screens, and operator interfaces incorporates HFE principles
  - HFE guidelines include those for observability, content, readability, and arrangement of displays

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## **Technical Evaluation: Controls and Displays (NUREG-1537 Section 7.6)**

The staff evaluated whether other controls and displays of important parameters (including reactivity) are readily accessible and understandable to the operator.

- Evaluation focused on two sets of controls & displays:
  - Controls & displays unrelated to manual protection
  - Controls & displays for manual protective actions
- The displays used at operator workstations, supervisor workstation, and main control board are digital displays
- Display & interface design incorporates HFE principles
- Both TRPS and ESFAS indications and manual actuation controls are located at main control board

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## **Technical Evaluation: Alarms (NUREG-1537 Section 7.6)**

The staff evaluated whether annunciators and alarms on the control console clearly show the status of systems (e.g., interlocks, TRPS & ESFAS initiation, and radiation)

- Alarms are integrated into the PICS display systems
- Stacklights produce audible alarm sounds and are programmed to represent both IU and non-IU alarms
- HFE design guidelines address the design of alarms
- Control room also contains a criticality accident alarm system and a panel for monitoring facility fire alarms

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## **Technical Evaluation: Administrative Controls (NUREG-1537 ISG & NUREG-1520)**

The staff evaluated whether the ability of SHINE operators to reliably implement administrative controls was adequately supported by SHINE's program for managing procedures

- SACs are incorporated into facility procedures
- Operating procedures are reviewed by management and controlled to ensure technical correctness
- Procedures are verified and validated prior to issuance for use within the facility

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## **Technical Evaluation: Administrative Controls (NUREG-1537 ISG & NUREG-1520)**

The staff evaluated whether the ability of SHINE operators to reliably implement administrative controls was supported by the training & qualification program

- Licensed operator training program contains topics on criticality control features and management measures
- Training is included within the areas of design features, reactivity, control systems, and uranium handling
- The operator training program utilizes a systems approach to training

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## Evaluation Findings and Conclusions

- HFE-related design and programmatic aspects for SHINE meet the HFE-related aspects of Criterion 6 within the specific context of the operator safety role
- HFE-related design aspects of control console and display instruments are acceptable because they:
  - meet the relevant NUREG-1537 criteria, and
  - are generally consistent with NUREG-0700
- HSI supports the manual initiation of safety systems
- Programmatic considerations are acceptable for:
  - procedures management
  - operator training & qualification

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*Note: backup slide(s) follow this point*

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## Regulatory Basis: Additional Information

- SHINE is defined as a utilization facility under 50.2
  - 50.34(f) only applies to those applications either pending in 1982 or made under Part 52
    - 50.34(f)(2)(iii) for a control room design reflecting state-of-the-art HFE not applicable
  - 50.55a(h)(3) requires meeting the requirements for safety systems in IEEE Std. 603–1991; section 5.14 addresses HFE via IEEE 1023-1988
    - However, this applies only to power reactors
- Regulatory basis does **not** require an HFE program





# Conduct of Operations

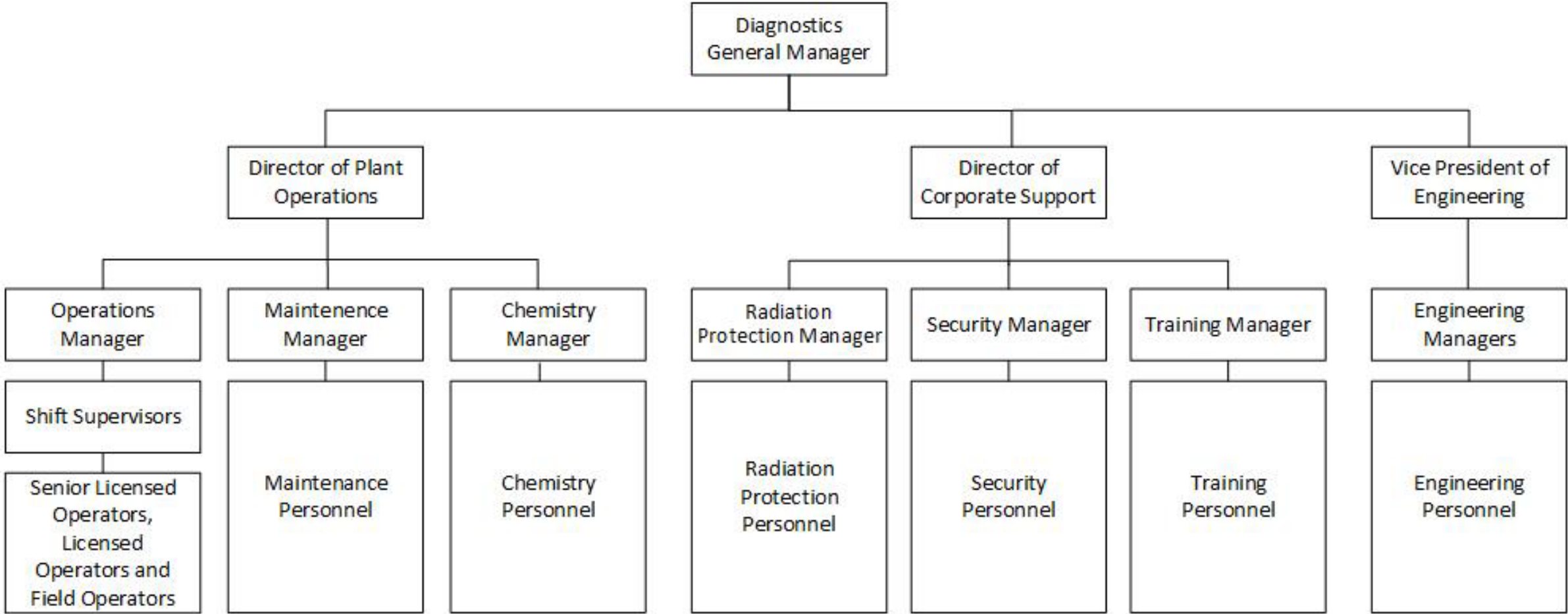
CATHERINE KOLB, SENIOR DIRECTOR OF PLANT OPERATIONS

# Outline

- Organization
- Review and Audit Activities
- Procedures
- Required Actions and Reports
- Records

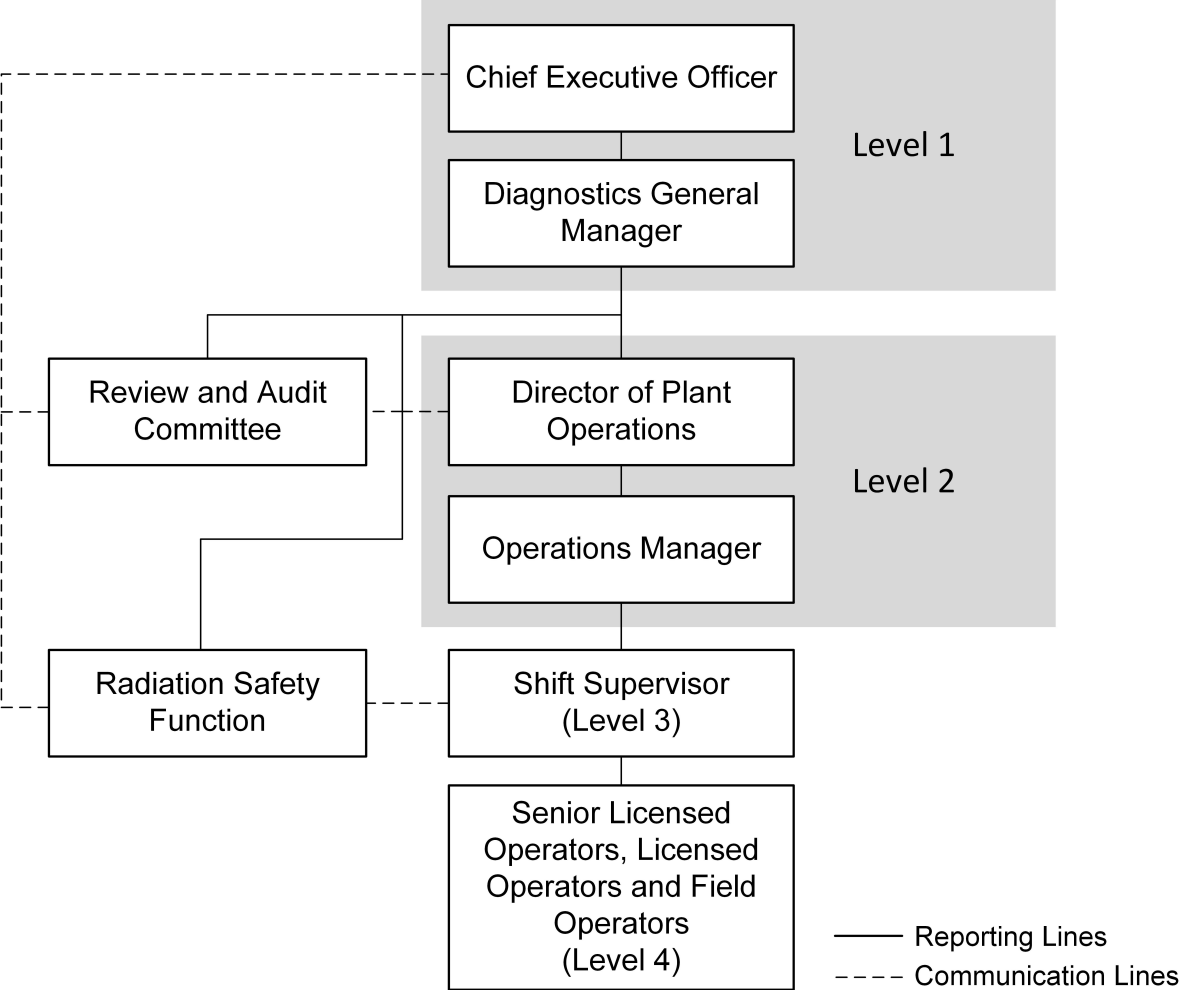
# Organization

## NORMAL ORGANIZATION CHART



# Organization

## TECHNICAL SPECIFICATION POSITIONS



# Organization

## MINIMUM STAFFING (PRESENT AT THE FACILITY)

- Shift Supervisor
  - Fills Technical Specification requirement for “Senior Licensed Operator”
  - Fills Emergency Plan requirement for initial “Emergency Director”
- Accelerator Operator
  - Must be present in the control room
  - Fills Technical Specification requirement for “Licensed Operator or second Senior Licensed Operator”
- Field Operator/Additional Accelerator Operator/Other Designated Individual (#1)
  - Fills Technical Specification requirement for “additional designated person”
- Field Operator/Additional Accelerator Operator/Other Designated Individual (#2)
  - Fills Emergency Plan requirement for initial “Emergency Communicator”
- Radiation Protection Individual/Other Designated Individual (#3)
  - Fills Emergency Plan requirement for initial “Radiation Safety Coordinator”
- Security Personnel
  - As required by the Physical Security Plan

# Organization

## OPERATIONS CONDUCT

- Safety Culture
- Operational Authority
  - Only authorized individuals manipulate controls or are present in control areas
  - Turnover processes are defined
  - Configuration control of the facility is maintained
- Conduct and Professionalism
  - Performance monitoring of licensed personnel is conducted
  - Ancillary duties that may interfere with abilities to safety and effectively operate the facility are not assigned
- Training and Continuous Improvement
- Procedures and Operator Aids
  - Procedure adherence is expected
  - Operator aids shall be accurate and controlled, and are not used as a substitute for procedures

# Review and Audit Activities

- Review and Audit Committee Composition
  - Minimum Membership
    - Chair (Diagnostics General Manager or Designee)
    - Engineering
    - Operations
    - Radiation Protection
  - May include non-SHINE employees where required expertise is not available from SHINE employees
  - Facility operations personnel (reporting to the Director of Plant Operations) cannot constitute a majority

# Review and Audit Activities

- Review Function
  - 10 CFR 50.59 safety reviews;
  - New procedures and major revisions having safety significance;
  - Proposed changes in facility equipment or systems having safety significance;
  - Proposed changes in, or violations of, technical specifications or License;
  - Violations of internal procedures or instructions having safety significance;
  - Operating abnormalities having safety significance;
  - Reportable occurrences; and
  - Audit/Assessment reports
- Audit Function
  - Facility operations for conformance to Technical Specifications;
  - Training and requalification program for operating staff;
  - Results of corrective actions affecting nuclear safety; and
  - Facility programs and plans



# Procedures

- Procedures provide direction for normal, abnormal and emergency situations
- Prepared, reviewed, approved, verified, and validated in accordance with document control processes and the Quality Assurance Program Description (QAPD)
- Procedure topics:
  - startup, operation, and shutdown of the irradiation unit;
  - target solution fill, draining, and movement within the SHINE Facility;
  - maintenance of major components of systems that may have an effect on nuclear safety;
  - surveillance checks, calibrations and inspections required by the technical specifications;
  - personnel radiation protection;
  - administrative controls for operations and maintenance and for the conduct of irradiations that could affect nuclear safety;
  - implementation of required plans (e.g., emergency, security); and
  - use, receipt, and transfer of byproduct material

# Required Actions and Reports

- Safety Limits
  - Pressure and temperature for the primary system boundary (irradiation units)
  - Pressure for process tanks containing irradiated uranyl sulfate (radioisotope production facility)
- Safety Limit Violation Required Actions
  - SHINE Facility operations shall be shut down immediately and operation shall not be resumed until authorized by the NRC
  - Reported to Level 2 management and the NRC
  - Safety limit violation report prepared, reviewed by the Review and Audit Committee, and submitted to the NRC

# Required Actions and Reports

- Events Requiring a Special Report
  - Release of radioactivity from the site above allowed limits;
  - Operations with actual Safety System settings for required systems less conservative than the limiting safety system settings;
  - Operation in violation of limiting conditions for operation (LCO) established in Section 3, unless prompt remedial action is taken as permitted in accordance with the LCO actions;
  - A Safety System component malfunction that renders or could render the Safety System incapable of performing its intended safety function;
  - Abnormal and significant degradation of the primary system boundary;
  - Abnormal and significant degradation in the primary closed loop cooling system and the light water pool; and
  - Observed inadequacy in the implementation of administrative or procedural controls such that the inadequacy causes or could have caused the existence or development of an unsafe condition with regard to operations
- Actions for Occurrence of Events Requiring a Special Report
  - The affected processes or areas of the facility shall be returned to normal conditions or shut down
  - If shut down, operation shall not be resumed unless authorized by Level 2 management
  - Reported to Level 2 management and NRC
  - Occurrence reviewed by the Review and Audit Committee

# Required Actions and Reports

- Operating Reports
  - Operating experience for each irradiation unit
  - Unscheduled shutdowns and corrective actions
  - Tabulations of major changes in the facility and procedures allowed under 10 CFR 50.59
  - Summary of radioactive effluents released
  - Summary of environmental surveys
  - Individual monitoring results required by 10 CFR 20.1502
- Other Special Reports
  - Permanent changes involving Level 1 or Level 2 management
  - Significant changes in the transient or accident analysis described in the FSAR
- Additional Event Reporting
  - 10 CFR 70.50 and 10 CFR 70.52, and SHINE-specific reporting requirements that meet the intent of Appendix A to 10 CFR Part 70
- Startup Report

# Records

- Lifetime Records
  - Gaseous and liquid radioactive effluents released to the environs;
  - Offsite environment-monitoring surveys required by the technical specifications;
  - Radiation exposure for all monitored personnel;
  - Drawings of the SHINE Facility; and
  - Records of reportable occurrences involving violations of safety limits, limiting safety system settings, and limiting conditions for operation
- Five Year Records
  - Normal SHINE Facility operation;
  - Principal maintenance operations;
  - Reportable occurrences;
  - Surveillance activities required by the technical specifications;
  - Facility radiation and contamination surveys where required by applicable regulations;
  - Radioactive material inventories, receipts, and shipments;
  - Approved changes in operating procedures; and
  - Records of meeting and audit reports of the review and audit committee
- One certification cycle
  - Records of retraining and requalification of licensed operations personnel

# **Advisory Committee on Reactor Safeguards**

## **SHINE Medical Technologies, LLC Operating License Application**

### **Chapter 12 – Conduct of Operations**

**Steven Lynch**  
Chief, Advanced Reactor Policy Branch  
Office of Nuclear Reactor Regulation

**July 20, 2022**

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## Scope of Review

- Section 12.1, “Organization”
  - Describes various levels of organization, including reporting and communication lines
- Section 12.2, “Review and Audit Activities”
  - Describes composition and qualifications; charter and rules; review functions
- Section 12.3, “Procedures”
  - Describes review and approval process for procedures, including changes to procedures
- Section 12.4, “Required Actions”
  - Describes the required actions, as provided in the technical specifications, to be taken
- Section 12.5, “Reports”
  - Provides the content and timing of submission of annual operating and special reports
- Section 12.6, “Records”
  - Describes the scope of record management program from identification to disposition

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# Regulatory and Guidance Framework Used

- The applicable regulatory requirements for the evaluation of SHINE's conduct of operations are as follows:
  - 10 CFR 50.34, "Contents of applications; technical information," paragraph (b)(6).
  - 10 CFR 50.40, "Common standards."
  - 10 CFR 50.54, "Conditions of licenses," paragraphs (i), (j), (k), (l), and (m)(1).
  - 10 CFR 50.57, "Issuance of operating license."
  - 10 CFR Part 20, "Standards for Protection Against Radiation."
- NUREG-1537, Interim Staff Guidance Augmenting (ISG) NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria."
- ANSI/ANS 15.1-2007, "The Development of Technical Specifications for Research Reactors"
- ANSI/ANS 15.4-2016, "Selection and Training of Personnel for Research Reactors."



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## Evaluation of Final Safety Analysis Report

- SHINE generally followed the guidance in ANSI/ANS 15.1-2007 and ANSI/ANS 15.4-2016, which is consistent with the information needs described in the ISG Augmenting NUREG-1537 to satisfy applicable regulatory requirements
- SHINE took some exceptions were taken to the guidance documents to account for SHINE not being a research or test reactor; having irradiation units containing an aqueous target solution; and having a production facility

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# Summary of Exceptions

- In Section 12.2.3, “Review Function, the NRC staff finds it acceptable that SHINE has excluded experiments from its list of items to be reviewed since it will not be conducting experiments at its facility.
- In Section 12.2.4, “Audit Function,” the NRC staff finds it acceptable that SHINE has included its quality assurance program description, physical security plan, and nuclear criticality safety program within the scope of items to be audited as this goes beyond the minimum provided in ANSI/ANS 15.1-2007.
- In Section 12.3, Because SHINE is not a reactor, the NRC staff finds it acceptable that the topics for which written procedures will be prepared, reviewed, and approved, will include topics related to SHINE’s IUs and target solution. The NRC staff also finds that it is acceptable for SHINE to exclude topics related to experiments since it will not be conducting experiments at its facility.
- In Section 12.4, Because SHINE is not a reactor, the NRC staff finds it acceptable for SHINE to use language encompassing operations and processes within both its irradiation facility (IF) and radioisotope production facility (RPF) as being within scope of reportable events and actions to be taken should a reportable event occur.

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# Summary of Exceptions

- In Section 12.5, for annual operating reports, the NRC staff finds the following deviations from ANSI/ANS 15.1-2007 acceptable:
  - Exclusion of the tabulation of new tests or experiments because SHINE will not be performing tests or experiments at its facility
  - Providing results of individual monitoring carried out by SHINE for each individual for whom monitoring is required by 10 CFR 20.1502, “Conditions Requiring Individual Monitoring of External and Internal Occupational Dose,” because this is more conservative than the criterion provided in ANSI/ANS 15.1-2007
- In Section 12.6, For the records to be maintained for five years or for the life of the component involved if less than five years, the NRC staff finds the following deviations from ANSI/ANS 15.1-2007 acceptable:
  - Exclusion of records for experiments because SHINE will not be performing experiments at its facility
  - Maintaining records for radioactive material inventories rather than fuel inventories because SHINE will have special nuclear material in the form of an aqueous target solution rather than heterogeneous fuel

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# Evaluation Findings

- SHINE has presented an organizational structure that reflects the complete facility organization from the license holder to the operations staff. All organizational relationships important to safety have been shown, including the review and audit function and the radiation safety function.
- The responsibility for the safe operation of the facility and for the protection of the health and safety of the SHINE staff and the public has been shown.
- Consistent with the requirements of 10 CFR 50.54, paragraphs (i), (j), (k), (l), and (m)(1), SHINE's minimum staffing ensures that manipulation of controls of the facility will be performed by licensed operators or senior operators as provided in 10 CFR Part 55
- SHINE describes the necessary experience, education, and training for each of the four qualifications levels and other technical personnel. SHINE also provides for radiation training consistent with the requirements in 10 CFR 19.12, "Instruction to Workers."
- SHINE has described a radiation safety organization that is acceptable. This organization has direct access to upper management and the review and audit committee to express concerns, if necessary. The radiation safety staff has the authority to interdict or terminate activities to ensure safety.

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# Evaluation Findings

- The review and audit committee members appear to be well qualified, with a wide spectrum of expertise. The committee membership includes provisions for including persons from outside the company.
- SHINE has proposed a charter and rules that describe the number of times the committee meets, the way the committee conducts business, the requirements for a quorum when voting, and the way the committee distributes its reports and reviews.
- SHINE has proposed a comprehensive and acceptable list of items that the committee will review and audit.
- SHINE has proposed a set of required procedures that is appropriate to operation of the facility, and that the process and method described by SHINE will ensure proper management control and proper review of procedures.

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# Evaluation Findings

- SHINE has defined a group of incidents as reportable events and has described the required actions it will take if the reportable event occurs. The definition of reportable events gives reasonable assurance that safety-significant events will be reported by the applicant.
- SHINE has proposed actions to be taken if a safety limit is violated or a reportable event occurs. The NRC staff has determined that SHINE will take whatever actions are necessary to protect the health and safety of the public.
- SHINE has described the content, the timing of the submittal, and the distribution of the reports to ensure that important information will be provided to the NRC in a timely manner.
- SHINE has described the types of records that will be retained by the facility and the period of retention to ensure that important records will be retained for an appropriate time.



# Startup Plan

THOMAS DRURY, COMMISSIONING COORDINATOR

# Overview

- Purpose
- Administration
- Facility Tests
- Irradiation Unit Tests



# Purpose

- Startup Testing is conducted to ensure the as-built facility conforms to the design and that the specified safety functions of structures, systems, and components (SSCs) are achieved.
  - Verify key parameters necessary for the safe operation of an irradiation unit (IU)
  - Verify key parameters necessary for the safe handling of special nuclear material outside the IU
  - Ensure that operating characteristics are well understood
    - Confirm calculational parameters
    - Establish operational parameters including setpoints
  - Ensure the safety of the plant is not dependent on the performance of untested SSCs

# Administration

- Performance of tests
  - Startup testing is conducted in accordance with approved test procedures and test plans
    - Acceptance criteria predefined
  - Led by qualified personnel
  - Deficiencies documented and dispositioned
- Startup test report
  - Methods and objectives
  - Comparison with acceptance criteria
  - Design and construction deficiencies
  - Justification for acceptance of non-conformances
  - Results of test
  - Submitted within 6 months of the completion of all startup testing activities

# Facility Tests

- Facility tests conducted to verify operation of systems outside of the IUs
  - Verify ability to handle uranium and produce target solution via performance of the first evolution of target solution preparation
  - Test and balance process vessel vent system flowrates to ensure adequate sweep gas flow for hydrogen mitigation
  - Verify operation of the vacuum transfer system's ability to transfer target solution between storage locations
  - Ensure functionality of the tritium purification system
  - Standby generator automatic start and load capability

# Facility Tests

- Facility tests conducted to verify design parameters
  - Direct dose measurements are compared to expected dose rates in accordance with Radiation Shield Test Program.
  - Operability of uninterruptible electrical power supply system (UPSS) in accordance with technical specifications
    - Voltage and specific gravity
    - Charger and inverter voltages
    - Capacity
  - Functionality of instrumentation for both safety-related and nonsafety-related control systems

# Irradiation Unit Tests

## OPERATIONAL CHARACTERISTICS

- Verify target solution vessel (TSV) filling and drain rates conform to design specifications
- Neutron driver extensively tested for leakage, operability, stability, and yield
- TSV off-gas system (TOGS)
  - Water holdup
  - Primary boundary leakage
  - Sweep gas flow rate
  - Iodine removal
- Primary closed loop cooling system (PCLS)
  - PCLS ability to automatically maintain temperature tested
  - Flow characteristics tested
  - Integrity tested by periodically sampling for radioisotopes indicative of leakage

# Irradiation Unit Tests

SUBCRITICAL ASSEMBLY SYSTEM NUCLEAR PHYSICS PARAMETERS  
OPTIMUM CONCENTRATION, CRITICAL HEIGHT, AND CALCULATIONAL BIAS

- Optimum Concentration
  - Calculations predict an optimum concentration (OC)
  - TSV to be filled four times with solution approximately 5% below to 5% above calculated OC
  - Fill two more times with concentration determined from interpolation of previous results
  - OC based on interpolation of previous results
- Critical Height
  - TSV filled with optimum concentration OC+5% and OC+10%
  - Comparison of critical height vs. concentration calculations
- Calculational Bias
  - Bias estimated in terms of uranium concentration and reactivity based on results from OC and critical height startup plans

# Irradiation Unit Tests

SUBCRITICAL ASSEMBLY SYSTEM NUCLEAR PHYSICS PARAMETERS REACTIVITY COEFFICIENTS

- PCLS reactivity worth
- TOGS holdup reactivity worth
- Temperature reactivity coefficient
- Void reactivity coefficient

# Irradiation Unit Tests

## NEUTRON FLUX DETECTION SYSTEM CALIBRATION

- Initial calibration is similar to annual calibration
- Without calibrated power and wide range neutron flux detection system (NFDS) channels, power is limited by limiting neutron production
- Few hour run at approximately 10 percent power
- Potential for intermediate power run
- Few hour full power run
- Additional full power runs at higher concentration/lower fill height to investigate detector sensitivity to solution geometry



# **Advisory Committee on Reactor Safeguards**

## **SHINE Medical Technologies, LLC Operating License Application**

### **Chapter 12.11 - Startup Plan**

**Michael Balazik**  
Project Manager/Inspector  
Office of Nuclear Reactor Regulation

**July 20, 2022**

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# Regulatory Basis

- Regulatory Requirements
  - 10 CFR 50.34, “Contents of applications; technical information”
    - (b)(6)(iii) Plans for preoperational testing and initial operations
  - 10 CFR 50.40, “Common standards”
  - 10 CFR 50.57, “Issuance of operating license”

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# Guidance and Acceptance Criteria

- NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Format and Content,” issued February 1996;
- NUREG-1537, Part 2, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors, Standard Review Plan and Acceptance Criteria,” issued February 1996;
- Final Interim Staff Guidance (ISG) Augmenting NUREG-1537, Part 1 and Part 2, for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors

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## Summary of Application (continued)

- Identified tests and measurements to
  - Verify safety significant facility parameters
  - Verify parameters for safe handling of special nuclear material
  - Validate operating characteristics of the facility
- Specific test plans will contain acceptance criteria
- Required to submit startup report
  - TS 5.8.4 requires startup report submission within 6 months of startup activities

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# Summary of Application (continued)

- Identified system testing for facility and IUs
  - Calibrations of equipment
  - System flow, fill, and drain rates
  - Leak rates (boundary integrity)
- Identified nuclear parameters:
  - Uranium concentration
  - Critical height
  - Temperature and void coefficients
  - TOGS/PCLS reactivity worth
  - Neutronic bias
  - Flux distribution
  - Radiation measurements

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# Evaluation Findings and Conclusions

- Identified plans to validate safety significant parameters
- Plan to develop acceptance criteria based on FSAR design information for the startup test procedures
- Submit startup report 6 months of completion of startup activities
- Implementation of the startup plan provides reasonable assurance the facility can operate as described in the FSAR
- NRC will conduct inspection activities to confirm readiness of the startup test program

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# Startup Test Program Inspection

- NRC staff is developing a SHINE facility specific inspection plan that includes inspection of the SHINE startup test program.
- Verification of acceptance criteria
- Inspection Procedure (IP) 69022, “Inspections of Operational Readiness During Construction of Non-Power Production and Utilization Facilities”
  - Operational Program Inspections – use existing operational IPs as guidance
- Apply certain guidance in IP 72401, “Part 52 Inspection of Startup Test Program”