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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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FRIDAY

OCTOBER 21, 2022

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

COMMITTEE MEMBERS:

RONALD G. BALLINGER, Chair

VICKI BIER, Member

CHARLES H. BROWN, JR., Member

VESNA DIMITRIJEVIC, Member

GREGORY HALNON, Member

JOSE MARCH-LEUBA, Member

JOY L. REMPE, Member

MATTHEW SUNSERI, Member

ACRS CONSULTANT:

DENNIS BLEY

KEN CZERWINSKI

STEPHEN SCHULTZ

DESIGNATED FEDERAL OFFICIAL:

CHRISTOPHER BROWN

ALSO PRESENT:

MICHAEL BALAZIK, NRR

JOSH BORROMEO, NRR

NORBERT CARTE, NRR

CATHERINE KOLB, SHINE

SCOTT MOORE, ACRS

RYAN MYERS, SHINE

TRACY RADEL, SHINE

BILL WATSON, SHINE

DANIEL ARIZAGA, SHINE

TABLE OF CONTENTS

P R O C E E D I N G S

9:30 a.m.

CHAIRMAN BALLINGER: All right. It's 9:30. Let's begin the meeting. This is a meeting of the SHINE Subcommittee of the Advisory Committee on Reactor Safeguards. I'm Ron Ballinger, Chairman of today's subcommittee meeting.

ACRS members in attendance are Charlie Brown, Greg Halnon, Jose March-Leuba, Joy Rempe, Matt Sunseri, and I see Vesna somewhere here, Vesna Dimitrijevic. And if I've missed somebody, I'm sure I'll get reminded.

MEMBER BIER: Yes, Ron.

CHAIRMAN BALLINGER: Yes, yes.

MEMBER BIER: This is Vicki Bier. I just joined, and I don't know if you saw my email. I will have to duck out for a while at around 11 Eastern.

CHAIRMAN BALLINGER: Yes, got it. Thanks again. We also have our consultants, Dennis Bley and Steve Schultz present. Chris Brown of the ACRS staff is the Designated Federal Official for this meeting.

During today's meeting, the subcommittee will have a discussion with the NRC staff and SHINE Medical Isotope, Incorporated, concerning process integrated instrument control system (PICS). They start up in any other remaining questions concerning life cycle. I might add that this is the last subcommittee meeting for this effort, so it's been a long road but we're almost at the end.

The rules for participating, part of the presentations by the applicant may be closed. We don't think that will be the case, but, if it is, we'll have to make arrangements to close the meeting.

The rules for participating in all ACRS, including today's, were announced in the Federal Register on June the 13th, 2019. The ACRS section of the U.S. NRC public website provides our charter, bylaws, agendas, letter reports, and full transcripts of all full and subcommittee meetings, including slides presented there. The meeting notice and agenda for this meeting were posted there. We have received no written statements or requests to make an oral statement from the public.

The subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the full committee. The rules for participation in today's meeting have been announced as part of the notice for this meeting previously published in the Federal Register.

Today's meeting is being held virtually over Microsoft Teams. A telephone bridgeline allowing participating for the public using their computer using Teams or by phone was made available. Additionally, we have made an MS Teams link process and password available on the published agenda.

A transcript of today's meeting is being kept. Therefore, we request that meeting participants on Teams and on the Teams call-in line identify themselves when they speak and to speak with sufficient clarity and volume so they can be readily heard. Likewise, we request that meeting participants keep their computer and/or telephone lines on mute when not speaking to minimize disruptions. The chat features on Teams should not be used for any technical exchanges. Let's see. I can control -- most everybody looks like they're muted.

Again, I'd like to note that this is our final SHINE Subcommittee interaction with the staff and SHINE. We do have a November 15th subcommittee meeting from 8:30 to 5, it's a whole day, in which the subcommittee will work on remaining memos and work on the draft final letter report. That subcommittee will be open to the public.

We'll now proceed, and Josh, I see you

there. So please give any opening remarks that you would like.

MR. BORROMEO: Thank you, Professor Ballinger. My name is Josh Borromeo. I'm Chief of the Non-Power Production and Utilization Facility Licensing Branch. Today you're going to hear presentations from the staff and SHINE on PICS, the process integrated control system, which is a non-safety related system for the facility. And you'll also hear an overview of the phased construction approach and also our associated license and controls the staff is putting in place to ensure a safe operation while SHINE moves from phase to phase of construction.

Now, I do want to recognize it's been a long road, right, and in our internal chat we were saying, okay, we've started these in February. So I wanted to recognize that we still have some work to do to get this thing over the finish line, but I do want to express my appreciation for all the hard work that the staff and SHINE has done to get us to this point. And I also want to highlight my appreciation for ACRS and ACRS staff for being flexible and identifying ways to efficiently work to get us through this review.

So with that, I'll turn it over to SHINE for their PICS presentation.

CHAIRMAN BALLINGER: Okay. Before we add again, we now have Ken Czerwinski, another one of our consultants in the chemistry area, that's joined the meeting.

Okay. Let's go.

MR. MYERS: Hello. My name is Ryan Myers. I'm an I&C engineer here at SHINE. Welcome to the process integrated control system, PICS, presentation.

Next slide, please. Here's a look at the topics that will be covered. First will be an overview of the PICS main functions, then PICS network security features. After that, we'll look at PICS interfaces with safety-related systems. Next, our PICS communications with vendor-provided non-safety related control systems. And, finally, we'll look at operator access to the PICS network using PICS workstations.

Next slide, please. Here's Figure 7.1-1 from the FSAR showing the instrumentation and control system architecture. The upper right corner of the figure shows the PICS external interfaces with safety and non-safety related systems. Unidirectional and bidirectional communications with PICS are captured here. The safety-related systems in the center of this figure were covered in previous NRC audit discussions. PICS communications with the supervisor and operator workstations and indication displays in the facility control room are shown at the bottom of the figure, along with PICS production facility HMI communications.

Next slide, please.

MEMBER BROWN: Could you go back to the other slide for a minute? This is Charlie Brown.

MR. MYERS: Sure.

MEMBER BROWN: I noticed, it's just a question and maybe you've got an overarching answer for this. This is the -- you primarily show Figure 7.1-1, which is the excellent representation of the safety systems that we addressed in the last meeting. The process control, process integrated control system has a big box with nothing in it, which not unexpected since that's separate. And there is a figure in the, I think it's 7.3-1, but that one is nowhere near what I call the detail that the 7.1-1 is for the safety systems. It's, fundamentally, some block diagrams with one line going everywhere, which leaves a little bit -- you talked about ethernet inside of your PICS operations, and it would be nice to hear a little bit about how integrated these overall PICS things is when we get to that point in the slides.

I'm just giving you a heads-up, there's a question I had relative to the detail and how integrated the -- because you do call it an integrated system and how diverse -- not diverse; that's the wrong word. I'm not looking for diversity. I'm looking for separation of functions because there's two or three dozen process systems that are part of this overall process integrated control system. And my question really boils down to is it a giant computer that's running all those giant set of servers where all the software is on one or two servers, or are they independent systems which feed independently into the control functions for the operators?

You don't have to answer that now. It's just when we get to the appropriate point. Did I get that across very well?

MR. MYERS: Yes.

MEMBER BROWN: Okay.

MR. BROWN: Excuse me. This is Chris Brown. It looks like you were trying to go to full screen. Can you -- this diagram is very small. Can you try to change the view?

MR. MYERS: Yes, I'm just having a challenge doing that. There we go. Sorry. It's my first time driving.

MEMBER BROWN: We've got our magnifying glass. A little humor to start the meeting.

MR. MYERS: So on to the next slide then. PICS is a non-safety related control system used by the plant operators to control and monitor facility equipment throughout the radiation facility and radioisotope production facility. PICS supports the facility control room which contains the operator workstations and the main control board.

The non-safety related instruments and controls used throughout the plant are wired to the local remote idle panels which then route back to the PICS main distribution switch in the server room over copper or fiberoptic cabling. The PICS HMI workstations, including five system-specific remote workstations, use thin clients connected to virtual machines running on a server in the server room.

Next slide, please.

MEMBER BROWN: Did that just answer part of my question?

MR. MYERS: I think so.

MEMBER BROWN: That these, all these 20 or 30, whatever it is, the large number -- and I'm not arguing about the number. You obviously have a lot of things you have to control. So, fundamentally, there's a giant server where all the software is located for these systems. They're not separate PLCs for every system. Is that a correct assumption, for other than the ones shown up in the upper block of Figure 7.3-1?

MR. MYERS: There are separate PLCs split up by system. On the PICS side, there are five separate, well, actually, seven PLCs and then three for TPS. Those are split up, but they do communicate. They're virtual machines, like HMI screens run through, are on a stratus fault tolerant server that's located in the server room.

MEMBER BROWN: Okay. So there is a -- so this is stuff is, fundamentally, fed into -- if that server fails, what happens? You lose all your controls?

MR. ARIZAGA: Sorry. This is Dan Arizaga, I&C engineer.

MEMBER BROWN: Yes.

MR. ARIZAGA: So, essentially, there is redundancy in that with multiple thin clients, so, if one of the servers goes down, you would have several backup servers that would be able to pick up, so you would have no interruption of the actual control PICS.

MEMBER BROWN: Okay. So you've got backups. So you've got parallel servers running, which are all up to date for whatever is going on so that the workstation operator can move from one to the other server, as needed, to carry on operations; is that correct?

MR. MYERS: Yes. It will switch to the backup server automatically if the primary server were to fail.

MEMBER BROWN: Okay, all right. Go ahead.

MR. MYERS: I can go into a little more detail as we progress.

MEMBER BROWN: Okay. That's fine. Thank you.

MR. MYERS: PICS network, architecture and security, did I get through this one? Okay. The most important PICS security feature is that there is no connection to the internet, and the PICS devices are not WiFi capable. PICS does have an outbound only connection through a one-way data diode to the PICS historian. The PICS manufacturing control network is separated from the SHINE business network behind its PLC, and its PLC communications are split into ten virtual local area networks, or VLANs, one for each of the ten PLCs.

PICS has physical security implemented, including the locking of control cabinets, the server room, and physically blocking unused network ports. The ethernet IP with CIP communication protocol used for PICS is widely used to secure plants worldwide. No remote access for monitoring or maintenance of the plant is allowed either.

Next slide, please.

MEMBER BROWN: Stay there for a minute. This is Charlie Brown again. You say the manufacturing network is segregated from the SHINE business network. Does that mean it's not connected?

MR. MYERS: It's not connected at all.

MEMBER BROWN: Okay. That's all I was looking for. Segregation could mean you have segregated software within your servers that allows you to operate, but you're totally disconnected. That's all I wanted to know. Thank you.

MR. MYERS: PICS interfaces with safety-related systems. The safety-related systems, the target solution vessel reactivity protection system, TRPS, and the engineered safety features actuation system, ESFAS, communicate with PICS through a one-way isolated rs485 Modbus gateway. While the information exchange is unidirectional from TRPS/ESFAS to PICS,

PICS does send two cyclic redundancy checks, CRCs, per Modbus message for error checking and verifying the identity of the data.

Under normal operating conditions, PICS allows operators to manually actuate TRPS/ESFAS controlled components. The PICS controlled relays have contacts in series with the TRPS/ESFAS controlled relay contacts, so the safety and non-safety system controls remain electrically isolated. TRPS/ESFAS can remove component power, causing the components to fail to their safe positions, regardless of PICS output state.

After safety actuations, the enabled non-safety switch must be physically moved from the disabled to the enabled position on the main control board by the operator before a component reset request can be sent from PICS. The actuation and priority logic in TRPS/ESFAS must not be prevented by higher-priority inputs before TRPS/ESFAS will reset the component, as requested by PICS.

The TRPS mode transition and component reset request signals are sent from PICS to the safety systems using a bit stream or binary pattern of discrete relay outputs that are decoded by TRPS/ESFAS. Unrecognized PICS output patterns will do nothing in

TRPS or ESFAS. PICS is designed so that it cannot fail or operate in a mode that could prevent the TRPS or ESFAS from performing its designated functions.

CHAIRMAN BALLINGER: This is Ron Ballinger. On bullet number one, two, three, four, five, PICS provides signals to TRPS/ESFAS to reposition components, da, da, da, da, da. Is this an area where errors of commission or omission can impact the safety side?

MR. MYERS: Can you --

MEMBER BROWN: Let me interpret his question for you. If the operator doesn't do something, does that affect the safety side --

CHAIRMAN BALLINGER: Yes, either intentionally or not intentionally.

MEMBER BROWN: Right.

MS. RADEL: This is Tracy. So the -- no, no operator action is needed to respond to an accident condition, so they don't need to do anything. We have assessed thoroughly to ensure that, if they do, anything that they do cannot impact the safety systems from performing their safety functions.

MS. KOLB: And this is Catherine Kolb. So the purpose of this is for the reset, which I believe we discussed at a previous meeting. So after an actuation from TRPS or ESFAS, you'd ensure that the non-safety, enabled non-safety switch was in the enabled position, and then you would be able to use the PICS component, the PICS interface to reopen components that had closed, for example to reset things that had actuated.

There's no time requirements associated with that in our design. There's no, you know, no analogs, like power reactors sometimes have time required actions in order for operators to do things. This is just recovering from an accident at the operator's discretion once the accident has been mitigated or otherwise dispositioned to be safe.

CHAIRMAN BALLINGER: Thank you.

MR. MOORE: This is Scott Moore. I just ask that each of the speakers identify themselves with a full name before speaking, at least for the first time. Thank you.

CHAIRMAN BALLINGER: Good point. Thank you.

MR. MYERS: Next slide, please. PICS vendor-provided non-safety related control system interfaces. There are several vendor-provided control system interfaces with PICS that provide the operators in the facility control room with important process monitoring information. Some of the vendor-supplied control systems include the neutron driver assembly system, NDAS; a super cell; and various auxiliary control systems. Again, the most important thing is that none of the PICS vendor-provided devices have internet connections. Similarly, no remote access is allowed. In unused communication, ports are blocked or disabled. Many of the vendor-provided control systems use ethernet, Modbus, or other industry standard protocols to communicate with PICS. The safety benefits of the object-oriented CIP protocol over ethernet IP are employed by many of the vendor-supplied control systems.

Next slide, please. Vendor-provided non-safety related control system interfaces continued. The Modbus connections tie into the PICS network via Modbus interface modules or gateways, which provide independently-configured communication ports specific to their devices and systems. PICS Modbus networks only communicate with read/write registers approved by the vendors. Like the plant equipment using internet IP with CIP, the building automation system, or BAS, equipment uses BACnet/IP, another protocol commonly used in plants for HVAC and system facility controls.

PICS monitors information from the non-safety related vendor provided super cell and radioactive liquid waste immobilization PLCs, along with radiation monitors throughout the plant. PICS communicates with the vendor-supplied NDAS control system through providing permissive signals and monitoring information.

Next slide, please.

MEMBER BROWN: Before you go on, this is Charlie Brown again. The super cell, I'm trying to think back to the facility figure. Are the super cells within the irradiation units, or is that a big separate -- I've forgotten.

MR. MYERS: That's on the RPF side.

MEMBER BROWN: Okay. So that's on the production facility side. And there's how many super cells, just one or I thought there were multiple super cells.

MR. MYERS: Just the one.

MS. RADEL: This is Tracy Radel. Just to clarify, there's one super cell that has ten individual hot cells within it.

MEMBER BROWN: Okay. That's what, I was trying to get to that. I was looking at your figures from the text. I saw a number of workstations for various super cells. Okay, I got it. Thank you.

MR. MYERS: PICS workstations and network access. Users who require access to the FactoryTalk View Site Edition Supervisory Control and Data Acquisition system will have independent accounts created on the manufacturing domain. When logging in to a PICS workstation, the operator's credentials are authenticated against the valid accounts on the manufacturing domain and workstation graphics are view-only when no user is logged in.

Each PICS domain user will be assigned to one of five domain groups, including maintenance, operator, supervisor, administrator, or quality. SCADA permissions are limited based on the assigned domain group.

In addition to domain groups, users are assigned to security areas which allow control of PICS equipment. Control room operators and supervisors are assigned to all security areas.

Next slide, please. And now for the final slide, PICS workstations and network access continued. A PICS workstation user can only take control of a remote HMI after access is granted by the control room supervisor. The control room supervisor can also take back control of the PICS equipment at any time. Each workstation and main control board thin client have their own ten-minute backup power supplies provided by a local UPS. The standby generator system should be providing backup power before the local UPS runs out of battery. If power to a remote operator workstation were lost, that thin client's virtual machine session would continue to run on the stratus fault tolerant server in the server room.

That concludes the PICS presentation. Thank you.

MEMBER BROWN: Can I ask -- this is Charlie Brown again. Can I ask another question or maybe two, if I can figure it out here.

MR. MYERS: Sure.

MEMBER BROWN: I just wanted to confirm something. I think you said this earlier, but I wanted to connect it with words in the FSAR. In Section 7.3.5, 7.3.3.5, that's the access control and cybersecurity section, second paragraph reads, the PICS and other vendor-provided non-safety related control systems do not allow remote access. You talked about that a minute ago. Let me finish the next point.

Paragraph six says vendor-provided non-safety related control systems communicate with the PICS via ethernet or other industry standard digital communication protocols. I'm assuming that the ethernet is, there is no connection of any ethernet. You're running an ethernet bus through the PICS. I think you told us that in the previous meeting. Is that correct? Is my memory correct?

MR. MYERS: Yes, it's a local internet hardwired connection within the plant itself.

MEMBER BROWN: Okay. But it's strictly a local interior internet communication systems, so you can control multiple systems.

MR. MYERS: Right.

MEMBER BROWN: There is no connection to that particular network or internet network to any remote networks.

MR. MYERS: Correct.

MEMBER BROWN: Outside the facility, outside the facility. I think you've said that. I just wanted to -- the words were a little bit dicey in terms of how it's phrased; that's all.

MR. MYERS: Yes, you're correct. There are no ethernet connections outside of the facility.

MEMBER BROWN: Okay, all right. Thank you. Let me see if -- go ahead.

MR. WATSON: Charlie, this is Bill Watson, interim I&C manager. I did want to correct the record on one point. There is an outbound data stream from PICS to the PICS historian for sending information, outbound only.

MEMBER BROWN: Yes.

MR. WATSON: That communication occurs through a data diode or what the NRC calls a deterministic device, so it, in no physical way, can even allow any kind of external communications to come in to PICS. It's basically a one-way, you know, hardware device. It only allows PICS to report, you know, performance data out to the historian. So I didn't want --

MEMBER BROWN: Go ahead, go ahead.

MR. WATSON: I just wanted to make sure we were clear on that point, that there actually is a connection but it is outbound only and it's a hardware outbound only. It can't be defeated in any way.

MEMBER BROWN: Yes, mentioned that a few minutes ago. I guess my question on that is -- how can I phrase this properly? You've probably read this, I've reiterated this many times. A hardware-based device can have bidirectional hardware-based devices, but it's configured by software. A true data diode is not configured by software. In other words, it's hardwired and it can only have one unit directional. Nothing from external can backfill through it or be captured somewhere else and then reverse that or turn it into a bidirectional.

So I presume the data diode interpretation in this is strictly one way of passing data in and only one thing to couple it and send it out, and there's no software package that configures that. It's hard configured.

MR. WATSON: That's absolutely correct in the case of the data diode that's used for PICS.

MEMBER BROWN: Okay. That's all I wanted to know. Thank you very much. And thank you all for doing that so I didn't have to say anything.

CHAIRMAN BALLINGER: So that was your last slide?

MR. MYERS: That's correct.

CHAIRMAN BALLINGER: Okay. If there aren't any questions from the members or consultants on this presentation, we can switch over. Here we are. We're already there. I don't know who is the presenter in this case.

MR. CARTE: Norbert Carte from I&C, NRR.

CHAIRMAN BALLINGER: I'm a slow reader. Thanks.

MR. CARTE: Once again, this is Norbert

Carte from the Instrumentation & Control Branch. We're assisting DANU in the review of the application.

Next slide, please. So, predominantly, the review involves the same reviewers as you've seen previously. However, the bulk of the review for PICS was done by me, although there was some minor involvement by others.

Next slide, please. We use the same set of guidance, obviously different sections, for our review of PICS. Next slide, please. I used red a little bit to highlight what's new and different from what you've seen before.

Next slide, please. So what we're looking now is at PICS. What you've seen before was basically HIPS, TRPS/ESFAS radiation monitoring systems.

Next slide, please. So the PICS description is actually a little bit segmented in the sense that there is some description in 7.3 and obviously 7.2, and as well as 7.6, which is the control console display instruments. Most of the control console and display stuff is addressed by HFE, but it is technically part of PICS, so it was covered in the SER section on PICS.

And, again, the SHINE facility has two distinct parts in a radiation facility and a refuel radioisotope processing facility and one control room and one PICS for everything. Well, yes, the TRPS is for each irradiation unit.

So the safety of the facility is, in part, defined by two things: the criteria on the PICS systems and the criteria on the protection systems. But the requirements that the protection system be independent from the PICS system is not a requirement placed on the PICS, it's a requirement placed on the protection systems, and that was covered separately. Now, there isn't necessarily a requirement that they be diverse or different, but they are just by the nature of the technologies used.

Next slide, please. So the following three slides are three depictions from the FSAR of what constitutes the PICS. I won't spend a lot of time on this, but this is a little bit more detailed and is a little bit what Charlie was asking about on the other slides.

So next slide, please. This is the gateway communication between the safety system and the non-safety and basically what it's showing is that there are two predominant communication paths; and, within those communication paths, there are multiple instances of one-way communication. So it's not possible to communicate effectively into the TRPS or ESFAS, and that is one of the things that ensures independence.

The other thing that ensures independence is that, in general, the safety systems are failsafe on loss of power and the safety actuation is to lose power. Those two relays are in series, as described in the previous presentation, so that's a little bit how, another way that the systems are independent. This is the digital communication independence that the series power relays are the actuation independence.

Next slide, please. So, in essence, the control board has some static displays, as well as some manual switches. What you see is a little bit the ESF, which has, it's the middle display. It has that little operate safe shutdown position for the enable facility operation key switch.

Next slide, please. So, again, we need to summarize a little bit the NRC's approach to safety regulation. So it's a layered approach, and, in that layer, we do certain types of review. So the application identifies the principal safety concerns, the design criteria effectively establish the performance objectives that, if met, will ensure that the reasonable assurance of adequate safety against the safety considerations. The design bases are, in effect, the functions and values performed by the system and used in the analysis to demonstrate that normal operation, as well as anticipated events, will not cause the performance criteria to be exceeded.

Then, finally, the last layer of the review, and this is predominantly where I&C falls in, is that the equipment performs the design basis functions and values and misbehaviors of the equipment do not exceed the assumptions in the safety analysis. So predominantly -- next slide, please -- our review is to ensure that the misbehaviors of the equipment do not violate the safety analysis. So that, in essence, required us to look at a subset of the design criteria in the FSAR, and what you see in the safety evaluation and summarized below is the subset of criteria that we looked at to ensure safety.

Next slide, please. So the safety analysis, and so, as we were summarizing before, in effect, a system, our view of the world is that there are two types of systems in a facility, ones that generate events and ones that either prevent or mitigate or alarm and notify about those events. So the analysis demonstrates that the protection system ensures that all events generated do not endanger the health and safety of the public, and the PICS review, the FSAR, includes an analysis of the HIPS equipment or a summary of the analysis of the HIPS equipment, which we did look at during the audit, and that summary concluded that the failure modes of the HIPS equipment were bounded by the safety analysis documented in the FSAR or summarized in the FSAR.

There were two sort of exceptions to that which impose additional requirements on the architectural design so that those failures would not exceed what was already analyzed. But that level of detail is not really necessary in the FSAR and, therefore, is not in the FSAR. It was looked at during the audit.

So, again, the PICS is independent from the TRPS and ESFAS by multiple ways, the digital communication we saw earlier, the series, relays for power to the controlled components. And the analysis of the failure, the effects of failures is described in the FSAR as summarized on this slide.

MEMBER BROWN: Norbert?

MR. CARTE: Yes.

MEMBER BROWN: You can correct me if I'm wrong, but I hope I'm not. When we say the PICS is independent from the TRPS and ESFAS, there are communications from the facility control room that go through the PICS, but it comes up through the hardware module or something like that, I've forgotten what it's called, for specific, but it's unidirectional type information. It's not stuff, it's control functions is what I'm saying. It's nothing that could interfere with the operation of the TRPS or ESFAS.

MR. CARTE: Right. Actually, maybe the wording on that slide is slightly --

MEMBER BROWN: Yes, I'm looking at Figure 7.1-1, and you can very clearly see that there are interactions from the workstations to the PICS and then go out up to that, whatever it's called, I can't read it. I don't have my magnifying glass right now.

MR. CARTE: Yes, technically, you're correct. The wording on this slide, it's not a bidirectional wording, and it's actually, I would say, incorrect. The TRPS and ESFAS are independent from PICS. The PICS is not necessarily independent from the TRPS. But our view is that any failure of the PICS would not inhibit the TRPS and ESFAS from performing its function and, in that sense, they're independent.

MEMBER BROWN: Yes, I got that.

MR. CARTE: There is some information --

MEMBER BROWN: I just wanted to point out the discrepancy; that's all.

MR. CARTE: Yes. So there is information that goes from the TRPS and ESFAS to the PICS and failures of that information would result in loss of that information to PICS. But the TRPS and ESFAS is failsafe, so if that information were missing, like sensor failures, then the TRPS would failsafe to the safe state. But, in essence, you're correct. That statement is wrong. TRPS and ESFAS are independent from PICS.

CHAIRMAN BALLINGER: Yes, this is Ron again. It seems like we're, Charlie and I, are kind of beating a dead horse on this, but this is the crux of the analysis after all.

MR. CARTE: Yes. And so we talked about, and I guess there was mention of the third. What I initially talked about was the digital communications, which is one way out from TRPS to PICS. I also mentioned the relays interrupting power to the controlled or protection devices, controlled and protection devices, we would say the actuated devices.

What was mentioned in the PICS discussion that was a third point was that there is a priority module in effect that prioritizes the non-safety inputs, and those non-safety inputs, if you examine the logic in TRPS, can only work when there is no manual or automatic safety actuation commanded by the protection system. And in those instances, you can then reset the protective action of the protection system. In other words, basically, the condition requiring the protective action needs to clear, for the most part, before you can reset.

MEMBER BROWN: I got that out of the reading of the FSAR and your SER.

MR. CARTE: Okay. Thank you. Next slide. So, in essence, the design bases is essentially included in Section 7.3.1, which describes the variables monitored and alarmed, the control functions, the interlocks and permissives that are performed by the PICS system.

Next slide, please. And based on the review of the independence aspects of the TRPS from PICS, as well as the detailed analysis by SHINE summarizing the FSAR, PICS equipment failures are all bounded by the analysis summarized in the safety analysis sections of the FSAR. We reached a conclusion that PICS performs its role in providing reasonable assurance of adequate safety.

Next slide, please. Are there any questions?

MEMBER BROWN: I'm trying to figure it out. I lost track of one of my questions here. This is Charlie again. Hold on for a second. Oh, okay. There was one area, and I understand what the FSAR said, it was in Section 7.3.1.3.11, and this is the target solution vessel protection in ESFAS and its relationship. There were words like safety-related components that are capable of being actuated by the TRPS or ESFAS but also have a non-safety related function related to production achieve their safe state by having power removed. And then the converse of that is safety-related components that are capable of being actuated but do not have a non-safety related production are not controlled directly by PICS, but there is -- the way I read this is, the TRPS does have a non-safety related function and it feeds those functions.

Can you explain -- it achieves a safe state as a result of what? A malfunction so that it can't affect the facility functions? You know what I'm talking about?

MR. CARTE: A little bit. Let me, I think the way to think about the scheme is a rod control system. So, basically, in a power reactor, PWR, rod control system, you have non-safety control of the rods, but the safety system removes power and the rods drop, and it goes to a safe state. And it's that same configuration on the TRPS and ESFAS. All of the safe states are achieved by loss of power, so, if you get failures in the TRPS, you remove power, and that includes sensor failures or self-diagnostic failures of equipment, and that's how safety is assured.

So, in essence, the non-safety side control is sort of irrelevant. All you're worried about is that the failures are either detected and protected against and/or do not exceed the assumptions in the safety analysis.

MEMBER BROWN: Let me -- okay, I got that. I'm looking at how it achieves it functionally. There was another sentence where it said, in other words, it has some connection to some production function, but then it says -- so it's sending information to a production function of some kind. Then it says should a safety actuation be required, the TRPS or ESFAS opens a contact in series with the power supply to whatever component it was interacting with, causing it to achieve its safe state also, regardless of the control signals from the PICS. I read that positively and that, if you have some production function going on, you get a trip, the TRPS will terminate that function by turning off its power supply via a relay contact.

MR. CARTE: Correct.

MEMBER BROWN: That's the way I read that sentence, and I don't have a problem with that, at least as long as that reflects satisfaction with whatever production is going on. I mean, SHINE proposed it, so I presume they've looked at that.

MR. CARTE: Right. That is correct.

MEMBER BROWN: Okay. So I understand what's going on correctly then.

MR. CARTE: Right. It's basically, everything follows the pattern of a rod control system.

MEMBER BROWN: Okay. I got it. I understand the analogy. Thank you. That's all I had. Ron, I'm done.

CHAIRMAN BALLINGER: Okay. Thank you. Are there any other questions from members or consultants on this presentation? Hearing none, now we need to shift topics and go into the phased startup presentation. So I guess SHINE needs to bring up their slides. Who's the presenter?

MS. RADEL: Hi, this is Tracy Radel. I'll be presenting on the phased startup.

CHAIRMAN BALLINGER: Thanks.

MS. RADEL: So here's the outline of what we'll go through today. I'm going to start out with the philosophy around phased startup operations, move into descriptions of each of the phases, and then more specifically into the IF systems, RPF systems, I&C systems, electrical aux, and then finally conclude with the safety analysis aspects.

Next slide. So the overall philosophy is to meet the national need for Moly-99 production as soon as possible while also ensuring all requirements related to public health and safety are met. We've proposed phased startup operations to provide flexibility for challenges that we expected to arise during procurement, installation, and testing.

The key considerations we had for the way the phases are structured were to ensure that all the design criteria and safety functions were met during all phases. Our goal was to simplify the process boundary isolations, as well as the confinement boundary isolations, and to minimize the impact on operating portions of the facility.

I do want to note that our procurement and installation philosophy was not inherently impacted by phased startup operations approach. SHINE is procuring the equipment for all irradiation units at the same time. No phasing on that. Fabrication for most of the equipment is naturally being done and set for batches because there are eight units' worth of equipment, resulting in a staggered delivery. And as challenges have been encountered in the fabrication process, we have prioritized the phase one equipment.

Equipment will be installed as soon as possible after it's received on site. So while the primary focus is on getting phase one equipment installed, we will not hold off installation of equipment for later phases if it is ready to go in and the construction team has bandwidth for installation.

Next slide. The phases are described here. So for phase one, the facility structure and nitrogen system structure fully installed, IUs one and two are fully installed, and when I refer to an irradiation unit, or IU, it includes the IU-specific instances of the subcritical assembly systems, the neutron flux detection systems, target solution vessel, off-gas systems, primary cooling systems like water pool system, and radiological ventilation Zone 1 equipment located in the cooling room. This includes both RVZ1r and RVZ1e equipment.

For phase one, the tritium purification system train A will be installed, and then the auxiliary and support systems, with the exception of the IU-specific instances of PCLS, LWPS, and RVZ1 equipment that were mentioned above. And then the radioisotope production facility systems, with the exception of the iodine and xenon purification and packaging and the radioactive liquid waste mobilization selective removal capabilities.

So Figure 1.1-1 of the phased startup supplement provides a visual representation of the phasing showing the physical areas for installation in each phase can be helpful for understanding what's installed for each phase of operation.

Next slide. Phase two brings in irradiation units three, four, and five and TPS train B. Phase three brings in irradiation units six, seven, and eight and train C of the TPS equipment, along with the RLWI selective removal capability and the material staging building. Phase four is bringing in the iodine and xenon purification and packaging capability.

Next slide. On the irradiation units specifically, they are designed and operated at a unit level. Each IU has unit-specific instances of ESFAS, NDAS, light water pool, irradiation biological shield; and each IU is supported by a unit-specific instance of PCLS.

The support system and process interfaces with the IUs are isolated to support the phased startup operation. Specifically, the auxiliary systems, RPCS, facility nitrogen handling system, facility chemical reagent system, nitrogen system, and radiological ventilation zone include isolations to support the phasing.

Next slide. In the tritium purification system trains, the TPS as a whole consists of three independent trains, and each TPS train supports specific NDAS units. These train divisions are supporting the phased operation, so each of these trains includes independent thermal cycling absorption process, or TCAP; the TPS NDAS interface lines; secondary enclosure cleanup systems; vacuum impurity treatment systems; connections to the NDAS secondary enclosure cleanup; and TPS gloveboxes.

The tritium confinement boundary for each TPS train is independent and isolated from the other TPS trains, and no portion of the tritium confinement boundary is shared between TPS trains. Isolations are provided at the TPS interface points to facility systems to allow the trains to be connected and commissioned without impacting other TPS train operation.

Next slide. On the RPF side of the facility, the RPF systems are installed to support phase one operation, with the exception of the IXP system and selective removal within the RLWI. Note the capability to solidify liquid waste is installed as part of phase one. During phase one through three operations, the IXP system is not installed and the IXP hot cell is exploited from the super cell containment boundary. Connections to the IXP system are isolated during phase one through three.

The capability of the RLWI system to remove the classification driving isotopes is not available during phase one and phase two operation. During phase one and phase two, liquid waste is stored in the subgrade. We do not anticipate having to solidify liquid waste prior to phase three operation due to the capacity of the storage within the RLWS. Waste solidifying during phase one and phase two may be higher dose and higher waste classification than waste solidified during phase three or four. Solidified liquid waste would be stored in the portholes prior to shipment to disposal site.

Next slide. During phased startup operations, the instrument and control systems are installed to the extent practicable, given the extent of equipment installation. IU-specific instances of the TPS reactivity protection system are brought online with the associated IUs and the applicable phases.

There are nine TRPS cabinets installed in the facility control room. All cabinets will be installed prior to phase one operations. Those cabinets are divided in the following way: So the first three cabinets are the division A, B, and C for IUs 1 and 2. The second set of three cabinets are division A, B, and C for IUs 3, 4, and 5. And the final set of three are the Division A, B, and C cabinets for IUs 6, 7, and 8. So the division amongst the TRPS cabinets does support phased startup operations.

The engineering safety feature actuation system is installed to support phase one operations. We did implement a new capability to disable the inputs that are not used during later phases. These disabled inputs are restored and verified to be operable prior to entering the technical specifications mode of applicability associated with the given input. Disabled inputs are listed in Table 7.5-1 of the supplement, and the safety functions not utilized during particular phases are listed in Table 7.5-2 of the supplement.

MEMBER BROWN: This is Charlie Brown. Can I ask you a question relative to the last bullet?

MS. RADEL: Yes.

MEMBER BROWN: I understand what you've just gone through, but the ESFAS is an overall facility piece of equipment, not like the TRPS which is identified with each IU. And I'm only bringing this up because of past experience of doing things piecemeal in my Navy programs when we were building submarines or aircraft carriers.

Your ESFAS is going to have all functions. You talked about disabling outputs. It's not just outputs, it's also inputs that you have to be careful of, depending on how they're used in the software. I've been there and done that and you've got to be -- all I'm doing is providing a little unneeded advice probably. It's just very difficult to ensure you don't have some stray piece of information come in and all of a sudden gum up the works.

I'm not disagreeing with the approach

you're taking. I totally agree with the phased approach. It's just a matter of, for an overall total facility system, which has all that information already built into the software, you're not going to be piecemealing that software. It should be complete when you start at the very beginning, and I've taken that's correct based on what you've just said. I'm just --

MS. RADEL: Just to clarify, the disable function is for the inputs into the system and is done through the maintenance workstation and verification of those inputs being disabled for a particular phase or enabled to support a particular phase.

MEMBER BROWN: I got that, but you've also got outputs.

MS. RADEL: Yes, so that is the --

MEMBER BROWN: You can't ignore that.

MS. RADEL: So that's the safety function, you know, the safety functions that wouldn't be actuating during particular phases. Those are very limited within the ESFAS.

MEMBER BROWN: Okay. I'm just, before you start lighting off the first three, you've just got to make sure those outputs are truly not going to affect anything, that's all, so that you don't mess up the systems that you are actuating. I'm just a grandfather offering advice.

MS. RADEL: I appreciate the advice. Thank you.

MEMBER BROWN: Okay. Thank you.

MS. RADEL: Okay. The IU-specific instances of the neutron flux detection system are brought online with the associated IU. The safety-related process radiation monitors are installed, to the extent practical, given the extent of equipment installation. There are safety-related process radiation monitors associated with the individual IUs, as well as the TPS trains, and those are installed as that equipment is brought online.

Safety-related process radiation monitors associated with the IXP cell are installed prior to phase four operations. Table 7.7-1 provides a detailed listing of the radiation monitor phasing.

Process integrated control system hardware is installed prior to phase one operations, with the exception of hardware associated with TPS trains B and C. PICS monitoring and controls associated with equipment that's not yet installed or not yet operable to support phase one are tested and placed into operation as required for the given phase.

Next slide.

MR. SCHULTZ: Tracy?

MS. RADEL: Yes.

MR. SCHULTZ: This is Steve Schultz. There are non-safety related radiation monitors associated with the PICS system. The PICS system reads them. Are they going to be installed? What is the schedule for --

MS. RADEL: All of the non-safety related radiation monitors, yes, are installed as part of phase one.

MR. SCHULTZ: I'm sorry. I didn't catch the last part of the response.

MS. RADEL: Sorry. Yes, the non-safety related radiation monitors are all installed as part of phase one.

MR. SCHULTZ: Great. Thank you.

MS. RADEL: Next slide. The normal electrical power supply system, or NPSS, and the uninterruptible electrical power supply system, UPSS, are installed in full to support phase one operations. Loads on the NPSS and UPSS that are not yet installed or not yet operable have the associated isolation device removed or placed into an out-of-service condition. Cabling associated with equipment not yet installed is installed to the extent practical with the power removed at the associated panel or load.

The non-safety related standby generator system is also installed to support phase one operations.

MR. BLEY: Tracy, Dennis Bley. Do you anticipate -- well, I guess you've already told us this. Never mind. I was wondering about the amount of unconnected cable that's going to be there, but it really doesn't matter. It will be from the source to where the equipment will eventually be installed for the most part?

MS. RADEL: The cabling and panels will be installed out to the remote panels as part of phase one and then --

MR. BLEY: And that includes the remote panels?

MS. RADEL: Yes, it includes the remote panels. And then the cabling beyond that will be installed depending on equipment installed.

MEMBER BROWN: Okay. Along with the final connection back to the power supply?

MS. RADEL: Yes. Auxiliary systems. The RVZ1 recirculating subsystems. Our RVZ1r units support individual IU cells and are installed with the corresponding IU. A portion of the RVZ1e subsystem is also installed with the corresponding IU that is the portion of the system that is located within the cooling rooms.

Supply lines from auxiliary systems that are supplying each of the irradiation units have manual isolation valves and blank flanges or caps to support phased startup operations. And because of normal variation and flexibility in facility operations, the auxiliary systems are designed to handle the variable loads without any modifications.

Next slide. For the accident analysis, a hazard evaluation was performed to identify new or different accident scenarios, including changes to likelihood or consequence of existing accident scenarios. The likelihood and consequence for these new or different accident scenarios were then evaluated and compared to the risk matrix and safety-related controls were applied to prevent or mitigate the accident scenarios in the method that was consistent with what's described in Chapter 13(a)(2) of the FSAR.

No new accident categories were identified as part of phased startup operations. And no increases to the consequences of existing accident scenarios covered in Chapter 13 of the FSAR were identified.

There were five new accident sequences within the existing accident categories that were identified and five existing accident scenarios were re-evaluated for increased likelihoods. Four new credited entry controls and three new credited administrative controls were added during phased startup operations to prevent the new or different accident scenarios.

And this is the final slide of my presentation. Any questions?

MEMBER SUNSERI: Tracy, this is Matt Sunseri. I've got a question for you. All these physical analysis controls seem pretty thought out to me. Can you speak a little bit towards the controls that you will have in place for personnel access, construction personnel access, operations personnel access, such that, for a lack of better word, I'll use the term unauthorized individuals aren't exposed to radioactive material or radiation and that the construction workers don't impede operators from getting where they need to be to operate the plant?

And one last component of that is what oversight of the construction activities will be in place such that they won't drift from their construction activities and work on operational equipment? That's a long one, but it's kind of the administrative controls that you're going to have.

MS. KOLB: Yes, this is Catherine Kolb. I'll respond to that question. So SHINE will implement our physical security plan, our radiation protection program, which includes access control to the facility. So if workers, construction workers, need to have regular access to the facility, they'll be badged and trained as rad workers if they need to to be able to access their normal work locations or else, per the provisions of the plan, they will be escorted by people who are trained and authorized, and we intend to fully implement those two plans.

The other question about oversight of construction activities, once the facility has its operating license for phase one, we would expect and have processes in place for people doing work for the facility to check in with the control room as if we were doing normal maintenance for the facility so that the operators are cognizant of large activities that are going on in the facility.

I know we don't have the general arrangement drawing in the presentation, but it is in the phase supplements. And you will notice that most of the activity is localized to the specific radiation unit cells that would be worked on during the phased approach, so we would not expect, you know, large construction activities to be taking place, you know, like throughout the facilities. So it should be, we are expected to be able to coordinate that during the phased approach installation activities.

MEMBER SUNSERI: Okay. That sounds reasonable to me. I was just thinking about when we talked through the plant a few weeks ago there was a couple of places, and I just remember one and I probably will get the equipment mixed, but I think the irradiation units were on one side and the tritium purification was on the other side of the hall in this real long hall, so I can imagine that might get pretty busy in there when you're operating half of it and working on the other half. Thanks.

MS. KOLB: Yes. I understand your point there, and your recollection is correct on the arrangement of the facility. You know, we intend to install everything that we can to the extent practical to minimize that, but, yes, we're just intending to implement the processes and procedures as we have described them.

MEMBER SUNSERI: Thank you.

MS. RADEL: Any other questions? Okay. Thank you.

CHAIRMAN BALLINGER: Hearing none, thank you very much. I think we would sort of be scheduled for a break around now, say at 11, if we were to go that far, but we only have one more presentation to go and then discussion. So why don't we go with this presentation, and then, if we think discussions are going to take a longer time, we'll have a break before that.

So unless I hear an objection from members, let's go with the NRC presentation. Thank you.

MR. BALAZIK: Can everybody hear me okay?

CHAIRMAN BALLINGER: I can hear you fine.

MR. BALAZIK: Perfect. Thank you. Good morning. My name is Michael Balazik. I'm the NRC project manager for SHINE in the Office of Nuclear Reactor Regulation within the Division of Advanced Reactors and Non-Power Production and Utilization Facilities. And this morning, I'll be presenting the staff's review of the phased approach to startup.

Next slide, please. Okay. So the regulatory requirements that the staff applied to this portion of the review were 50.34, contents of applications and technical information; 50.40, common standards; and probably the most important one, 50.57, the issuance of operating license.

Next slide, please. Guidance hasn't changed. We pretty much use the standard guidance we've been using for this entire review. NUREG-1537 and the final Interim Staff Guidance for licensing of radioisotope production facilities.

Next slide, please. All right. So, quickly, I'll just go over a summary of the application. Tracy provided a lot more detail than I would. Back in January of this year, SHINE did supplement the SR-described four-phase approach to startup operations. This phased approach is staggered over a couple of years and planned to be completed in the 2025 time frame.

So within the supplement, SHINE describes the impacts, the technical impacts, along with information differences for each chapter of what I'll call the full design facility FSAR. Within the supplement, SHINE identifies equipment isolation points and the isolation methods for each phase for the different equipment.

So some of the chapters that were most

impacted by this phased approach to startup were Chapter 4, Chapter 7, Chapter 9, and 13.

Next slide, please. All right. Just continuing on with a summary of the application. Back in February of this year when we provided an overview to ACRS full committee on the SHINE review, we did talk about this phased approach to startup. And I remember one member saying that, you know, this is kind of analogous to plug and play. I can't remember if he said that, but that's, you know, pretty much our look on a majority of these items.

So the irradiation units, they're designed and operated as independent units. The TPS, which consists of three independent trains to support the IU operation, so TPS train Alpha will support phase one, and trains Bravo and Charlie, they'll support the operation of the subsequent phases.

With the exception of the iodine and xenon purification and packaging system and the radioactive liquid waste isolation, all systems for the production facility will be installed to support phase one operations. And for instrument and control for TRPS, it's IU-specific, and some of the inputs for the ESFAS, which Member Brown was talking about, is an entire facility system and, along with PICS, some of those inputs are disabled and brought on as the phases come in.

And discussing Chapter 13, there were five new accident sequences that were identified and five existing sequences that had an increase in likelihood. The new accident sequences were improper target solution routing, damage to a TPS train, damage to the process vessel vent system, Talk's interface, and back flow of target solution to the IXP.

And the likelihood increase that was evaluated by SHINE, there were heavy load drops on the TPS, heavy load drops on an operating irradiation unit or Talk cell, and a heavy load drop on the radioactive liquid waste isolation enclosure super cell. And then, of course, as the phases go in, as construction is continued, you know, there's an increase in the fire, the irradiation facility or the radioisotope production facility.

Next slide, please. So how we started our approach to this review is that we wanted the exact same staff members to review the phased startup approach that reviewed the full design. So for our technical and safety review, the NRC staff reviewed the information, the SHINE supplement, against regulatory requirements, regulatory guidance and acceptance criteria, that I discussed earlier. Staff evaluated the effect of the phased approach of startup on the sufficiency of the facility descriptions, design basis, facility operation, and SSCs, and as the facility as a whole. And we also reviewed the kinds and quantities of radioactive material expected to be produced in the operation of the SHINE facility and the means for controlling and limiting radioactive exposures within 10 CFR Part 20.

We also reviewed the methods and sufficiency of system level isolations for the different phases just to ensure safe operation of facility and health and safety of the workers and public.

Next slide, please. Okay. We did perform an audit. Right now, we're just finishing, just some final touches on that is in draft form right now. We can share that with members if requested. We're hoping to have that issued here very soon.

I'll say that, early on in our review, we had some areas of perceived risk significance in some of those areas where the human system interfaces and training of operators, because there will be a lot going on in these different phases, that we wanted to make sure, like the operators, you know, there are minimal distractions to them while operating the facility.

Tracy and Charlie discussed this earlier on disabling and enabling instrumentation and control inputs. Also, with construction, there will be increased clean operations with heavy loads during operation and also on radiological dose to workers on completing construction. And what we looked at is if there was a construction going on in an adjacent IU cell, you know, what would those doses look like to that individual in there.

Next slide, please. So 10 CFR 50.57, which is issuance of operating license, it requires that each license issued by the Commission to include appropriate provisions with respect to uncompleted items of constructions required to ensure that the operation during the period of the completion of such items will not endanger public health and safety. So in their response to an RAI, SHINE did provide phased specific listing of installation and functional testing that was needed to support each phase of the operation. And the staff is imposing a license condition to ensure that the operation of these subsequent phases will not commence until the uncompleted items are completed and that NRC oversight of completion of these uncompleted items is maintained.

So next slide, please, is the actual license condition that we're proposing. The first part of this just points to the supplement submitted by SHINE, and then the two conditions below talk about, you know, 14 days prior to planned commencement of operation of the next phase, that SHINE has to notify the NRC in writing that all uncompleted items of construction have been completed. And item B there talks about SHINE providing updates to the NRC after issuance of the operating license, which, you know, would authorize phase one. Every six months, SHINE needs to provide the NRC an update on the information and the status of the schedule for completion of uncompleted items of construction. And we could use this information to inform our oversight inspection activities for SHINE.

And last slide here, these are evaluations and conclusions that SHINE did describe the design of the systems and identified major features or components affected by the proposed phase approach to startup, also that the process is performed; operating procedures and equipment; use of the facility; provide reasonable assurance that they'll comply with Part 50 and Part 20 regulations and that the health and safety of the public will be protected during the phased approach to startup; and, 50.40, the issuance of the operator license will not be inimical to the common defense and security of health and safety of the public and that the descriptions and discussions of the SHINE systems affected by the approach are sufficient to meet the applicable regulatory requirements and acceptance criteria for issuance of an operating license.

That's my last slide. Are there any questions?

MEMBER HALNON: Yes, Michael. This is Greg Halnon. Do you guys have a plan for how you're going to do the oversight during this time frame? There was some discussion whether Region III would be doing it or Region II. Since you'll have operation and construction going on at the same time, will there be different oversight centers or --

MR. BALAZIK: Yes, Member Halnon. Right now, Region II is the lead for the construction activities at SHINE. Once we get into that pre-operational readiness, there's a combination of Region II oversight activities and NRR oversight activities. So office of NRR has the lead for the pre-operational readiness.

Now, for these parts of construction, we haven't figured out exactly who would have the lead on these inspection activities and what the inspection activities look at this time. So I can't give you a definite answer who is going to have the lead on this.

MEMBER HALNON: Okay. I think, as you go forward and figure that out, we'd be interested in at least seeing the documents or some kind of plan. I'm not sure that the Operations Subcommittee wants a full-blown meeting or anything, but let's stay in touch and, when you get that set, communicate it with me.

MR. BALAZIK: Yes, sir. I got it. Appreciate it. Any other questions?

CHAIRMAN BALLINGER: This is Ron Ballinger. With respect to that request, do you anticipate the timing for that?

MR. BALAZIK: I think that would be based on SHINE providing us the information when they would be, you know, ready to move to the next phase. But --

CHAIRMAN BALLINGER: Okay. So that's long after, long after we're done with the letter, right?

MR. BALAZIK: Long is a relative term. I don't know if SHINE wants to chime in on their planned schedule.

MS. RADEL: Yes, so this is Tracy Radel. We're approximately a year or so out from substantial completion, roughly, as far as receipt of the operating license, you know, subsequent to that.

CHAIRMAN BALLINGER: I would consider that long compared to December.

MR. BALAZIK: Yes, sir, I do agree with that. Thank you, Tracy.

CHAIRMAN BALLINGER: Okay. So absent further questions by members or consultants, we need to now ask for public comment. If you are a member of the public and you're listening and would like to make a comment, please state your name and make your comment, reminding, I think, that if you're on the phone you have to use the star 6 procedure to get access.

So are there members of the public out there that would like to make a comment? Apparently none.

Okay. So we are, more or less, at the end of the presentations. I don't think we need a closed session, so now I think we need to just open up the discussion for any other comments or discussion points that members would like to deal with. Deafening silence. Okay.

MEMBER DIMITRIJEVIC: Ron, this is Vesna.

CHAIRMAN BALLINGER: Vesna, how are you?

MEMBER DIMITRIJEVIC: Good. How are you doing?

CHAIRMAN BALLINGER: Your name is not on this list for some reason.

MEMBER DIMITRIJEVIC: I don't know why. I can see my name on the list.

CHAIRMAN BALLINGER: Okay, all right.

MEMBER DIMITRIJEVIC: I was thinking maybe we can devote some short time on just discussing how can we help you in writing this letter and do you have some structure in mind, you know, so that we can get ready for writing --

CHAIRMAN BALLINGER: Yes. I sent a note out to the members probably late last night. The way I see it, we now have, with the exception of two of the memos, all of the memos may have ML numbers, and so those are available. And my plan is to use those memos as not only the starting point but the major input for the letter and any other comments, which I've asked people for -- from time to time, members have sent paragraphs or such and such to me related to what might be in the letter. Like I said last night, there are various vintages. So if there are members that have additional comments or issues related to what might be in the letter, then I'd appreciate those because, come next week or starting this weekend, I'll be putting together the draft letter.

Now, the format will be, unless I hear something different, there are no showstoppers, no buts, that would be in the letter that would require response from the staff, I don't think. And so the front-end of the letter, we already have some of that, some of the background that we've seen before. And so then the conclusion will be quite simple in words we approve and then some minimal discussion that hits the high points and then a referral because all of the memos will be attached to the final letter. So what it amounts to is a summary up-front and then the detailed references also included in the letter.

So that's the general format, and I'd appreciate comments from members related to that because I'm going to start doing it tomorrow.

MEMBER DIMITRIJEVIC: So this was one of my, actually, curiosities. Every writer has, you know, comments or suggestions or conclusions in the front. You don't plan to put those in the final letter, you're just going to reference other letters?

CHAIRMAN BALLINGER: No, no, I'm sorry. I guess I wasn't detailed enough. There will be a section after the results and the conclusions and recommendation for sort of, I guess I would call it general comments, I'm not sure I'd want to use the word suggestions, that would contain the kinds of things that we've had discussions of at the various subcommittee meetings, and that's where input, the little paragraphs and the like that we've asked people to provide, would be very important.

So, yes, there will be, you know, again, since we don't anticipate, at least right now, any what I call showstoppers, the buts, that's just a for information section, in effect.

MEMBER DIMITRIJEVIC: Yes. You know, I was just thinking that these comments we have provided throughout the sessions, some of them are different types, you know. Like, for example, some are suggestions, something we would like to see later, you know. For example, Charlie had the comments on the electrical system, which he asked for the, you know, the changes. So I was sort of wondering because we're having these different type of comments --

CHAIRMAN BALLINGER: Yes, we'll have to reconcile --

MEMBER DIMITRIJEVIC: -- define the categories. I wasn't sure what's the best way to organize them, you know.

CHAIRMAN BALLINGER: I'm sure that, during our discussions of the draft, we'll get that all reconciled.

MEMBER DIMITRIJEVIC: All right, okay. So then next --

CHAIRMAN BALLINGER: We got to have a strawman to shoot at first.

MEMBER MARCH-LEUBA: This is Jose. The way I envisioned it was we would have all the memos, the full memos, in the appendices.

CHAIRMAN BALLINGER: Yes, yes.

MEMBER MARCH-LEUBA: Any comments, any recommendations, any conclusions that you would like to see on the main body of the letter, on the area responsible for the memo, it would be convenient for Ron if you write two or three paragraphs that you'd ask him to say this is the summary of what the memo says that I think merits inclusion in the body of the letter.

CHAIRMAN BALLINGER: Yes, that's, you know, we've asked that question quite a few times and asked for input, and we've gotten some input. But we'll ask it again, yes. That would be very, very helpful because, other than that, I will use the memos themselves, which also contain these kinds of comments. But it would be a lot easier if, now that we've had the complete set of presentations, where, if a member would like to provide a paragraph or so, that would be very helpful. That's my story and I'm sticking to it.

MEMBER BROWN: I had one question, Ron. Is this meeting on the, whatever day it is, the 15th, is that an in-person meeting, or are we going to be trying to do this all day by virtual?

MEMBER REMPE: No, it's in person. We decided that several months ago. Of course, if someone wants to, they can still stay and do it remotely, but there will be some folks in the room is what we decided.

MEMBER BROWN: Okay. I was just trying to confirm that that week was going to be an in-person week. I wasn't at the meeting so --

CHAIRMAN BALLINGER: Yes, I think the invitation was just sent out for anybody that wants to do remote, but yes.

MEMBER BROWN: Yes, okay. That's all I had.

MEMBER HALNON: So, Ron, this is Greg. Now I can kind of understand why you asked me to revise one of the memos.

CHAIRMAN BALLINGER: Oh, wait a minute, hold on a minute. Revising the memos, no, please.

MEMBER HALNON: Well, I mean, it's not the actual issues, it's what we expected for the follow-up. If we don't, you know, sometimes time heals some of these comments and then --

CHAIRMAN BALLINGER: Right, yes.

MEMBER HALNON: -- come up that don't really warrant anymore time being spent on it.

CHAIRMAN BALLINGER: Yes, yes.

MEMBER HALNON: I assume you'd like to make sure the memos are up to date from the standpoint of what we want follow-up and what we don't, kind of to Vesna's question, what --

CHAIRMAN BALLINGER: Well, I think now I'd have to ask Larry or Chris about this. I think those memos now have ML numbers, and so those are kind of in violet unless something else, unless we can -- I don't know what we would do if somebody wants to change a memo.

MEMBER REMPE: This is Joy. I mean, Larry and Chris can give you ultimate, but I would say that, no, those were a snapshot in time, and perhaps the letter can say these were a snapshot in time and these, you know, this letter has our final comments that we want to mention about this review.

CHAIRMAN BALLINGER: Yes, that's --

MEMBER REMPE: I think that's what we've done in the past.

CHAIRMAN BALLINGER: -- you know, the sort of one- or two-paragraph vehicle is a way to do that.

MEMBER HALNON: Okay. And that was where I was going with it. So in a paragraph, that should be the endpoint. I mean, that's finally where our mind is at relative to any issues that we have, both specific and general.

CHAIRMAN BALLINGER: Yes. A lot of these chapters are sort of interwoven, if you will, and so it's entirely appropriate to have a different outlook once you've heard them all.

MEMBER HALNON: Okay. And --

MEMBER DIMITRIJEVIC: So, Ron, when you said now, we definitely don't have showstoppers, but if there's suggestions for the changes in the chapter, like Charlie did on electrical, then what's happening with those?

CHAIRMAN BALLINGER: Well, if they're

suggestions, again, I need to make sure I'm not violating a rule, if they're suggestions, the applicant can either say, okay, we'll do that or, no, we won't do that. That will be at the staff's or the applicant's discretion. People can correct me if I'm wrong.

MEMBER REMPE: Well, I would point out that we only provide suggestions to the staff, right?

CHAIRMAN BALLINGER: Yes, yes.

MEMBER REMPE: I mean, we can make comments to the applicant, but our charter is to help the staff review.

CHAIRMAN BALLINGER: Yes, yes, yes.

MEMBER BROWN: If there's anything we want a response from the staff for, we ought to say it in your memo, not in one of the enclosures. It ought to be brought up to the memo and we ask for a staff response to our memo; that's all.

CHAIRMAN BALLINGER: And I think that actually has happened for many of them.

MEMBER BROWN: Yes, that's the way we've done all of our letters, so we sent a letter out, a report, and we ask for a response or we don't. If we want a response, then we get it. And if we've got suggestions, we ask for a response.

CHAIRMAN BALLINGER: Yes, yes.

MEMBER BROWN: This is not complicated.

CHAIRMAN BALLINGER: No, hopefully.

MEMBER HALNON: And the purpose of the final memo is to give the Commission our overall impression of the license application; is that correct?

MEMBER REMPE: That's true, except it's a letter, it's not a memo.

CHAIRMAN BALLINGER: It's a letter, it's a letter.

MEMBER BROWN: It's a letter report.

MEMBER HALNON: Yes, that's words. But the letter report.

MEMBER BROWN: It's a regular letter report.

MEMBER HALNON: Yes, okay.

MEMBER REMPE: But I'm bean-counting memos, Ron. You've said we've had all but a couple. I know they're posted out there, but we're going go actually go through how many? Isn't it like going to be four or five, depending on what's happening with this space --

CHAIRMAN BALLINGER: No, two or three.

MR. BROWN: Four. Four memos are left:

cyber, life cycle, I&C, and help me, Jose. Oh, tech specs, tech specs.

CHAIRMAN BALLINGER: Yes.

MEMBER REMPE: Isn't there a Chapter 7 also or something?

MR. BROWN: Yes, I&C. That's four.

CHAIRMAN BALLINGER: Yes. And there's potentially a fifth, but I haven't decided, and that is related to the phase approach. I waited until after the presentations, and I'm going to think about that a little bit, and it would be nice to hear from the members on this. I'm leaning towards not having a separate memo on the phased approach but including discussion in what we would call the preamble and some of the discussion in the letter because, in effect, what the phased approach is is just a different method of construction. Maybe I'm reading things wrong, but it would be nice to hear from other members on what their opinion would be.

MEMBER HALNON: It's not all that different than what's going on in Vogtle or any other multi-unit plant, so I don't see anything special about it. It's just a matter of making sure that they complied.

CHAIRMAN BALLINGER: Yes, yes, that's what

I'm coming down to, but there are other opinions probably. Oh, Scott Moore. Scott, you've raised your hand.

MR. MOORE: Yes, Chairman Ballinger. Previously, the staff had asked for the Committee's final report on SHINE by the end of December. Are they still looking for the report on that same time line?

CHAIRMAN BALLINGER: I haven't heard anything different, but we have an informal after this meeting, and I'm sure we can confirm that. But I think, Josh or Michael, can you confirm that?

MR. BORROMEO: That seems like a reasonable time, but we can discuss if there's resource issues at our informal afterwards.

MEMBER REMPE: This is Joy. And what would be a reason for us to delay? We've gotten all the information we need, and we have planned our schedule, and so I wouldn't, even if the staff decides, well, we can wait until, it would be February if we don't do it in December because January we don't have a full Committee meeting. So is there a reason that we wouldn't want to try and meet that deadline, Scott?

MR. MOORE: No, and I wasn't suggesting

that. The only -- I just wanted to confirm that that is when the staff needed the final report. And the only reason I'd say that the Committee should delay would be if there's new information or if the staff hasn't responded to anything yet, and I'm not aware of any of that.

CHAIRMAN BALLINGER: Right. So unless death or plague occurs, December is it.

MEMBER REMPE: You know, with all the pandemic stuff, don't say plague.

CHAIRMAN BALLINGER: I didn't say pandemic. I said plague.

(Laughter.)

MEMBER REMPE: Never mind.

CHAIRMAN BALLINGER: Okay. So we've had our discussion. Once again, I'd like to thank the staff and the applicant and our staff actually for seeing this through, and we're approaching the end, and I'm looking forward with some fear and trepidation to the November meeting where we have a discussion.

So if there aren't any further questions, I think we need to close off this meeting. But, Chris, should you and I and --

MR. BROWN: I have a separate invite. Check your --

CHAIRMAN BALLINGER: Oh, it's a separate invite. Okay.

MR. BROWN: Yes.

CHAIRMAN BALLINGER: All right. We're good.

MR. BURKHART: Hey, Ron, this is Larry. Do you want to have an opportunity for public comment?

CHAIRMAN BALLINGER: Did that.

MR. BURKHART: Okay, all right. Sorry.

CHAIRMAN BALLINGER: Did that and didn't hear anything. Okay. So thanks again everybody, and we'll see Josh and whoever in a few minutes.

(Whereupon, the above-entitled matter went off the record at 11:16 a.m.)

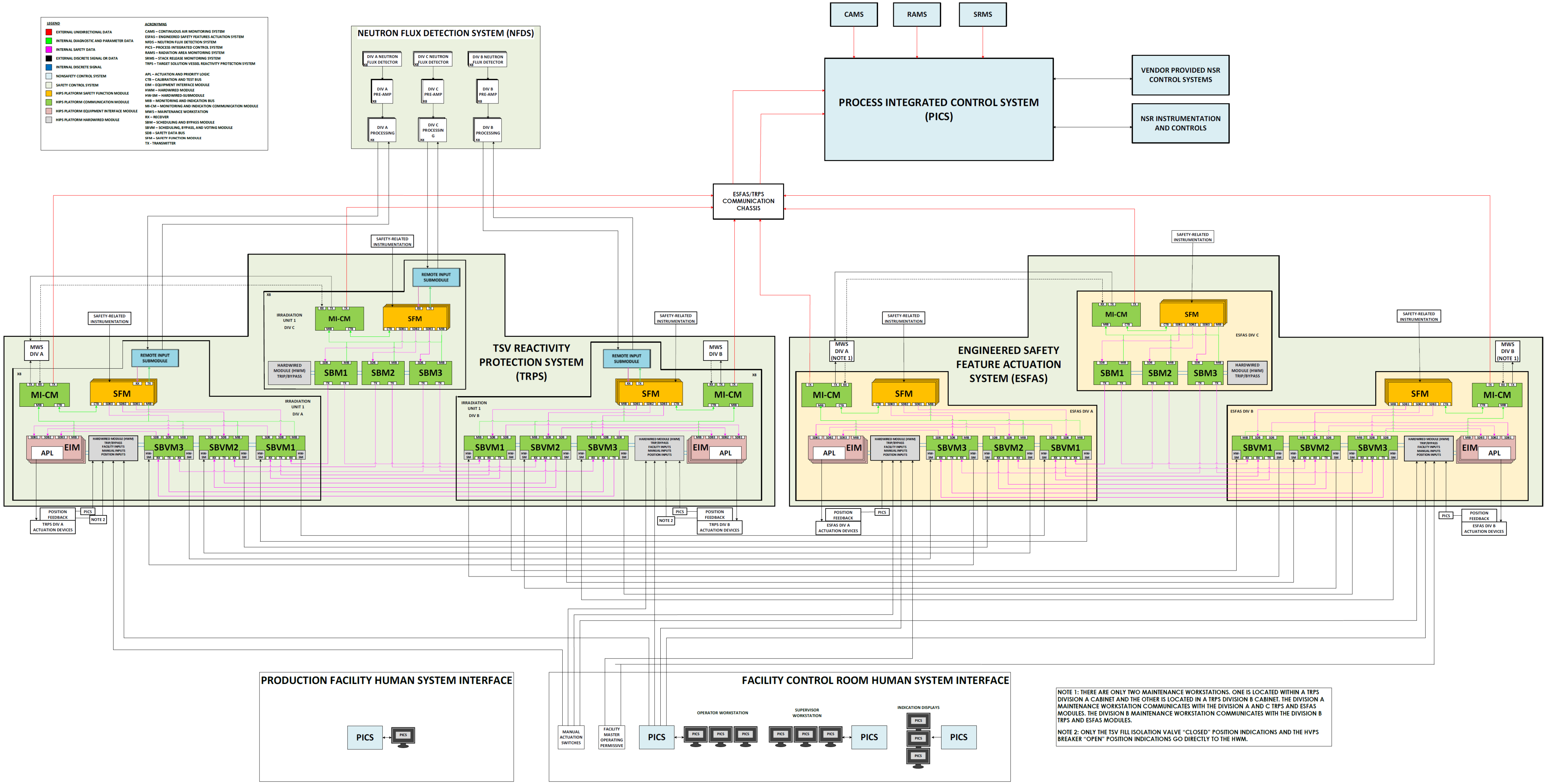
Process Integrated Control System (PICS)

RYAN MYERS, I&C ENGINEER

Outline

- PICS Overview
- PICS Network Architecture and Security
- PICS Interfaces with Safety-Related Systems
- PICS Vendor-Provided Nonsafety-Related Control System Interfaces
- PICS Workstations and Network Access

PICS Overview



PICS Overview

- PICS is a nonsafety-related digital control system whose principal functions are to control and monitor facility systems and components within the irradiation facility (IF) and radioisotope production facility (RPF).
- A portion of the PICS supports the main control board (MCB) and operator workstations in the facility control room (FCR) by receiving operator commands and collecting and transmitting facility information to the operators.
- The PICS system network routes signals to the main distribution switch located in the server room.
- Information from the FCR, remote input/output (RIO) cabinets, remote human machine interface (HMI) panels, programmable logic controllers (PLCs), vendor-provided control systems, and virtual machines communicate through the main distribution switch with a combination of copper and fiber optic cabling.

PICS Network Architecture and Security

- PICS has no connection to the internet and no Wi-Fi capable devices.
- The PICS manufacturing control network (MCN) is segregated from the SHINE business network.
- The PICS PLC communications on the MCN is split into 10 separate virtual local area networks (VLANs), one for each of the 10 PICS PLCs.
- PICS cabinets are locked requiring a key administratively controlled by Operations personnel.
- PICS server room which houses the PICS ControlLogix PLCs and servers, has restricted access.
- Unused ports (e.g., Ethernet, USB) are physically blocked or electronically disabled.
    - The port keys are controlled by Operations personnel.
- Ethernet/IP with CIP (common industrial protocol) is the communication protocol used for communication between the PICS PLCs, RIO racks, servers, workstations, and thin clients.
    - CIP is widely used to secure plant networks.
- Electronic access to PICS is not available from outside the site.

PICS Interfaces with Safety-Related Systems

- The target solution vessel reactivity protection system (TRPS) and engineered safety features actuation system (ESFAS) provide signals to PICS via a one-way isolated nonsafety-related Modbus gateway.
- PICS normally has manual electrically isolated control of TRPS/ESFAS controlled components.
- PICS provides valve and damper position indication to TRPS/ESFAS for verification of completion of protective function through electrically isolated relay outputs.
- PICS provides mode transition signals to TRPS, when manually initiated by the operator.
- PICS provides signals to TRPS/ESFAS to reposition components, when manually initiated by the operator and the main control board enable nonsafety switch is in the “enable” position.
- Both the mode transition and reposition request signals from PICS are encoded using a bitstream method with a pattern of discrete relay outputs that are then translated by TRPS/ESFAS.
- PICS is designed so that its failures cannot directly or indirectly impact the ability of the TRPS or ESFAS to perform its safety functions.

PICS Vendor-Provided Nonsafety-Related Control System Interfaces

- PICS interfaces with several vendor-provided nonsafety-related control systems which consist of the neutron driver assembly system (NDAS) controls, supercell controls, and various auxiliary control systems.
- There are no internet connected or Wi-Fi enabled devices for the vendor-provided equipment.
- Like PICS, the vendor-provided nonsafety-related control systems do not allow remote access and include the capability to disable unneeded networks, communication ports, and removable media drives, or provide engineered barriers.
- Vendor-provided nonsafety-related control systems communicate with PICS via Ethernet, Modbus, or other industry standard digital communication protocols.
- Many of the PICS vendor equipment interfaces communicate with CIP over Ethernet/IP, utilizing the protocol's built in safety features.

PICS Vendor-Provided Nonsafety-Related Control System Interfaces

- PICS Modbus connections to vendor-provided control systems use custom configured gateways to only read from or write to vendor-approved addresses.
  - The plant's power supply systems interface with PICS via Modbus.
- The building automation system (BAS) provides control for many of the ventilation and facility systems.
  - BAS provides information to PICS for monitoring only using BACnet/IP, a building automation and HVAC industry standard.
- PICS communications with vendor-supplied supercell and radioactive liquid waste immobilization (RLWI) system PLCs are read-only communications used for monitoring purposes only.
- The NDAS control system receives permissive signals from the PICS to allow or disable use of the system and provides information to PICS for monitoring.
- PICS monitors vendor-supplied nonsafety-related radiation monitors throughout the plant.

PICS Workstations and Network Access

- Users who require access to the FactoryTalk View (FTV) Site Edition (SE) Supervisory Control and Data Acquisition (SCADA) system will have individual accounts created on the manufacturing domain.
  - Users are required to set a password for their manufacturing domain account.
    - When users log in to PICS with their unique credentials, their accounts authenticate against the manufacturing domain.
  - When no user is logged in, graphics and alarms are view-only, with no control/interactive functions available.
  - Domain users will only be assigned to one domain group.
    - The five domain groups are Maintenance, Operator, Supervisor, Administrator, or Quality.
- In conjunction with domain groups, users will be assigned to security areas which will coincide with various equipment areas in the SHINE production facility.
  - This will allow SHINE to give certain user accounts limited control of PICS equipment.
  - Facility control room operators and supervisors will be assigned to all security areas.

PICS Workstations and Network Access

- Users will not be able to log in or operate remote HMI locations without being granted access by the facility control room supervisor.
  - The facility control room supervisor can take back control of the PICS equipment at any time.
- In the event of a power outage, each operator workstation has a local uninterruptable power supply (UPS) capable of supplying 10 minutes of backup power, by which time, the standby generator system (SGS) will be fully engaged providing power
  - The operator workstation thin client sessions are not lost with a local loss of power, they continue to run on the Stratus fault tolerant server (ftServer) in the server room.

Phased Approach to SHINE Facility Operations

TRACY RADEL, VICE PRESIDENT OF ENGINEERING

Outline

- Philosophy
- Phase Descriptions
- Irradiation Facility Systems
- Radioisotope Production Facility Systems
- Instrumentation and Control Systems
- Electrical Power Systems
- Auxiliary Systems
- Accident Analysis

Overall Philosophy

- Purpose: Meet the national need for Mo-99 production as soon as possible while also ensuring all requirements related to public health and safety are met
  - Provide flexibility for challenges that may arise during procurement, installation, and testing
- Key considerations:
  - Ensure that all design criteria and safety functions can be met
  - Simplify process boundary isolation strategy
  - Simplify confinement boundary isolation strategy
  - Minimize impact on operating portions of the facility

SHINE

Procurement and Installation Philosophy

- The SHINE approach to phased startup operations does not inherently affect how SHINE is approaching procurement and installation
  - Equipment for all eight irradiation units (IUs) being procured at the same time
  - Fabrication for most equipment is naturally being done in sets or batches, resulting in staggered delivery
  - As challenges are encountered in the fabrication process, equipment for Phase 1 will be prioritized
- Equipment will be installed as soon as possible once it is received on site

Phase Descriptions

- Phase 1:
  - Facility structure (FSTR) and nitrogen purge system (N2PS) structure
  - IUs 1 and 2, including IU-specific instances of the subcritical assembly system (SCAS), neutron flux detection system (NFDS), target solution vessel (TSV) off-gas system (TOGS), primary closed loop cooling system (PCLS), light water pool system (LWPS), and radiological ventilation zone 1 (RVZ1) equipment located in the cooling room
  - Tritium purification system (TPS) train A
  - Auxiliary and support systems, with the exception of IU-specific instances of PCLS, LWPS, and RVZ1 equipment located in the cooling room
  - Radioisotope production facility (RPF) systems, with the exception of iodine and xenon purification and packaging (IXP) and radioactive liquid waste immobilization (RLWI) selective removal capabilities

Phase Descriptions

- Phase 2:
  - IUs 3, 4, and 5, including IU-specific instances of the SCAS, NFDS, TOGS, PCLS, LWPS, and RVZ1 equipment located in the cooling room
  - TPS train B
- Phase 3:
  - IUs 6, 7, and 8, including IU-specific instances of the SCAS, NFDS, TOGS, PCLS, LWPS, and RVZ1 equipment located in the cooling room
  - TPS train C
  - RLWI selective removal capability
  - Material staging building
- Phase 4:
  - IXP capability

Irradiation Facility Systems

IRRADIATION UNITS

- IUs are designed and operated at the unit level.
  - Each IU has unit-specific instances of the SCAS, NDAS, light water pool, and irradiation cell biological shield (ICBS), and each IU is supported by unit-specific instances of the PCLS and TOGS.
  - Support system and process line interfaces with the IUs are isolated to support phased startup operation (i.e., interfaces with IUs 3 through 8 are isolated during Phase 1 operation, interfaces with IUs 6 through 8 are isolated during Phase 2 operation).

Irradiation Facility Systems

TRITIUM PURIFICATION SYSTEM TRAINS

- The TPS consists of three independent trains and each TPS train supports specific NDAS units.
  - Each TPS train includes independent train specific instances of the isotope separation system (Thermal Cycling Adsorption Process [TCAP]), TPS-NDAS interface lines, secondary enclosure cleanup (SEC), vacuum/impurity treatment subsystem (Vac/ITS), NDAS SEC, and TPS glovebox.
  - The tritium confinement boundary for each TPS train (including the TPS glovebox, SEC, isolation valves, TPS-NDAS interface lines, and tubing up to isolation valves) is independent and isolated from the other TPS trains; no portion of the tritium confinement boundary is shared between TPS trains.
  - Isolation is provided at TPS interface points to facility systems to allow TPS trains to be connected and commissioned without impacting operating TPS trains.

Radioisotope Production Facility Systems

- RPF systems are installed to support Phase 1 operations, with the exception of the IXP system and the RLWI selective removal capability.
- During Phase 1 through Phase 3 operations, the IXP system is not installed within the IXP hot cell, and the IXP hot cell is isolated from the supercell confinement boundary.
  - The interfacing process and supporting system connections to the IXP system are isolated during Phase 1 through Phase 3.
- The capability of the RLWI system to remove classification-driving isotopes is not available during Phase 1 and Phase 2 operations.
  - During Phase 1 and Phase 2, liquid waste is stored in the subgrade radioactive liquid waste storage (RLWS) system tanks prior to transfer to RLWI in order to maximize the decay time and limit the volume of solidified waste requiring disposal.
  - Waste solidified during Phase 1 and Phase 2 may have higher dose rates and higher waste classifications than wastes solidified during Phase 3 and Phase 4.

SHINE

Instrumentation and Control Systems

- During phased startup operations, the instrumentation and control (I&C) systems are installed to the extent practicable given the extent of equipment installation.
- IU-specific instances of the TSV reactivity protection system (TRPS) are brought online with the associated IU in the applicable phases.
  - The nine TRPS cabinets are installed in the facility control room (FCR) prior to Phase 1 operations but are brought into operation with the corresponding IU phasing as described in Chapter 1.
- The engineered safety features actuation system (ESFAS) is installed to support Phase 1 operations.
  - During phased startup operations, inputs to the ESFAS for equipment that is not required to be operable are disabled using the maintenance workstation (MWS).
  - These disabled inputs are restored and verified to be operable prior to entering the technical specification mode of applicability associated with the given input.

Instrumentation and Control Systems

- IU-specific instances of the neutron flux detection system (NFDS) are brought online with the associated IU in the applicable phases.
- The safety-related process radiation monitors are installed to the extent practicable given the extent of equipment installation.
  - Safety-related process radiation monitors associated with individual IUs (inputs to TRPS) and TPS trains (inputs to ESFAS) are installed during the phase associated with that IU or TPS train.
  - Safety-related process radiation monitors associated with the IXP cell (input to ESFAS) are installed prior to Phase 4 operations.
- Process integrated control system (PICS) hardware (i.e., cabinets, power supplies, controllers, programmable logic controllers [PLCs]) is installed prior to Phase 1 operations, with the exception of hardware associated with TPS trains B and C.
  - PICS monitoring and controls associated with equipment that is not yet installed or not yet operable to support Phase 1 operations are tested and placed in operation as required for a given phase.

Electrical Power Systems

- The normal electrical power supply system (NPSS) and uninterruptible electrical power supply system (UPSS) are installed in full to support Phase 1 operations.
  - Loads on the NPSS and UPSS that are not yet installed or not yet operable in Phases 1, 2, or 3 have the associated isolation device removed or placed in an out-of-service condition.
  - Cabling associated with equipment that is not yet installed or not yet operable for a given phase is installed to the extent practicable with the power removed at the associated panel or load.
- The nonsafety-related standby generator system (SGS) is installed in full to support Phase 1 operations.

Auxiliary Systems

- RVZ1 recirculating subsystem (RVZ1r) units support individual IU and TOGS cells and are installed with the corresponding IU.
- Portions of the RVZ1 exhaust subsystem (RVZ1e) located in the cooling rooms are installed with the corresponding IU.
- Supply lines from auxiliary systems include manual isolation valves and blind flange or caps to support phased startup operations.
- Auxiliary systems are designed to handle the variable loads without modifications.

Accident Analysis

- A hazard evaluation was performed to identify new or different accident scenarios, including changes to likelihood or consequences of existing accident scenarios.
- The likelihood and consequences for these new or different accident scenarios were then evaluated and compared to the risk matrix and safety-related controls were applied to prevent or mitigate the accident scenario, in a method consistent with that described in Chapter 13a2 of the FSAR.
- Phased startup operations do not result in any new accident categories or increased consequences from existing accident scenarios.
- Five new accident sequences were identified, and five existing accident scenarios were reevaluated with increased likelihoods.
- Four new credited engineered controls and three new credited administrative controls are added during phased startup operations to prevent the new or different accident scenarios.

SHINE

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Protecting People and the Environment

Advisory Committee on Reactor Safeguards

SHINE Medical Technologies Operating License Application

Chapter 7 – Instrumentation and Controls PICS

October 21, 2022

Norbert Carte

Office of Nuclear Reactor Regulation

I&C Technical Review Team

- **Dinesh Taneja –** Senior Electronics Engineer (HIPS, ESFAS, RMS)
- **Norbert Carte –** Senior Electronics Engineer (TRPS, NFDS, PICS)
- **Duane Hardesty** - Sr. Project Manager

  (Technical Specifications)
- **Rossnyev Alvarado** – Electronics Engineer

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

SAFETY EVALUATION OVERVIEW

Chapter 7 Safety Evaluation

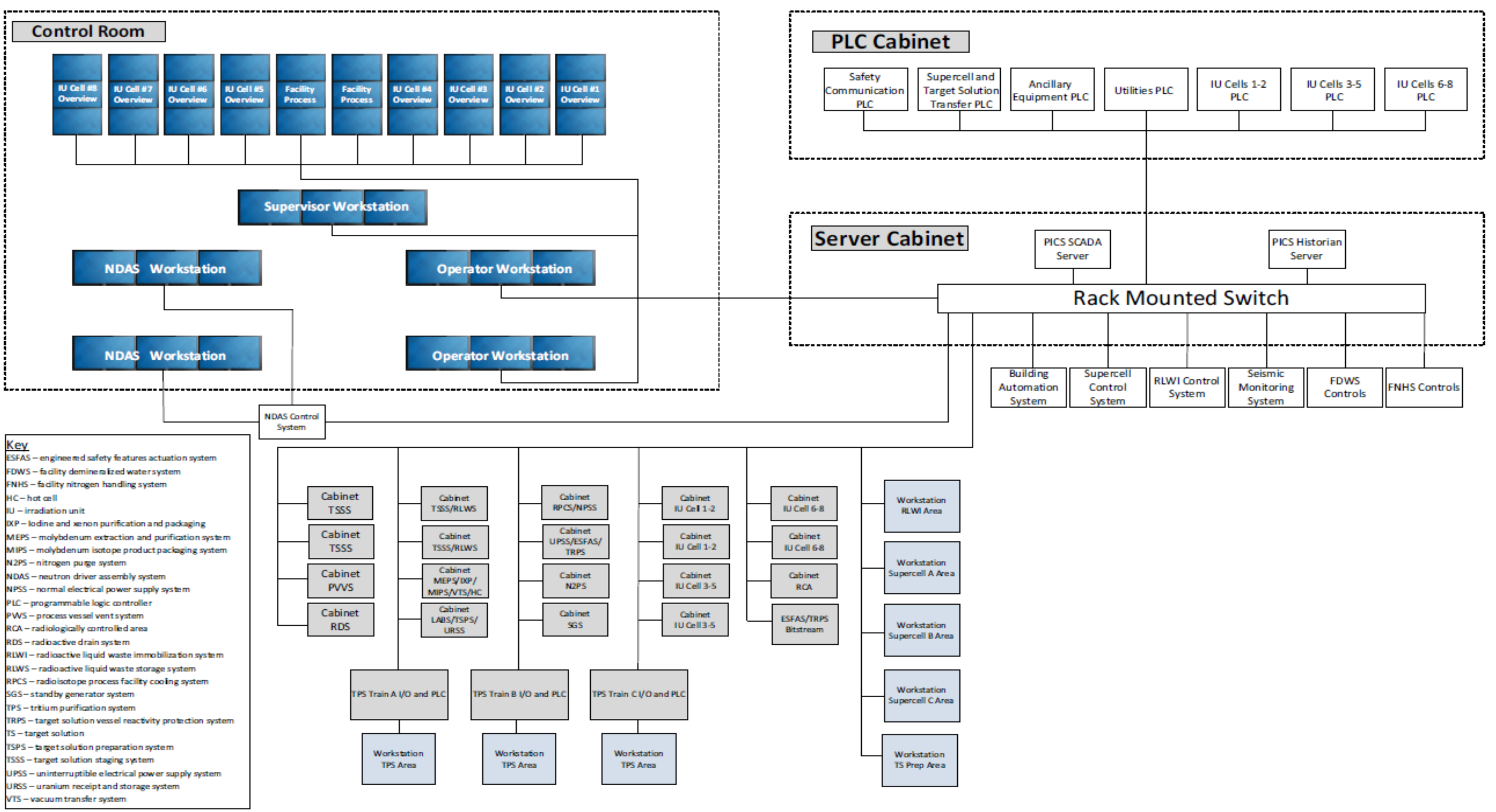
- Current Scope
  - PICS
- Previous Briefings
  - I&C Design Criteria
  - Highly integrated Protection System (HIPS)
  - Target solution vessel reactivity protection system (TRPS)
    - neutron flux detection system (NFDS)
  - Engineered safety features actuation system (ESFAS)
    - radiation area monitoring system (RMS)

PICS Description

- FSAR Sections
  - 7.3, “Process Integrated Control System”
  - 7.6, “Control Console and Display Instruments”
- SER Section 7.4.3, “Process Integrated Control System”
- SHINE Facility
  - Two Distinct Parts (IF & RPF)
  - One Control Room & one PICS (with many parts)
- Protection Systems (i.e., TRPS & ESFAS) & Control Systems (i.e., PICS) are:
  - Independent
  - Diverse

PICS Systems

Figure 7.3-1 – Process Integrated Control System Architecture



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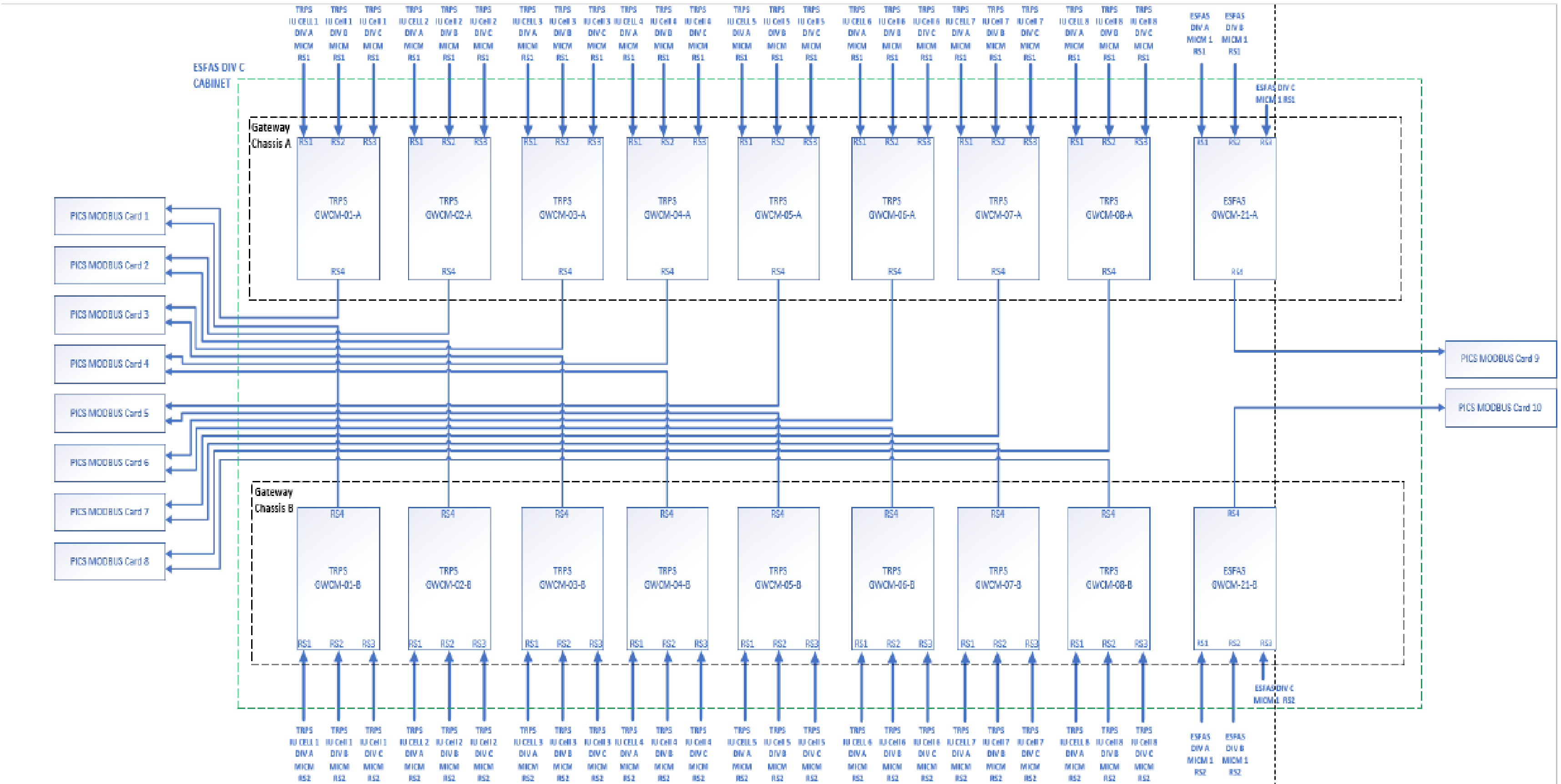
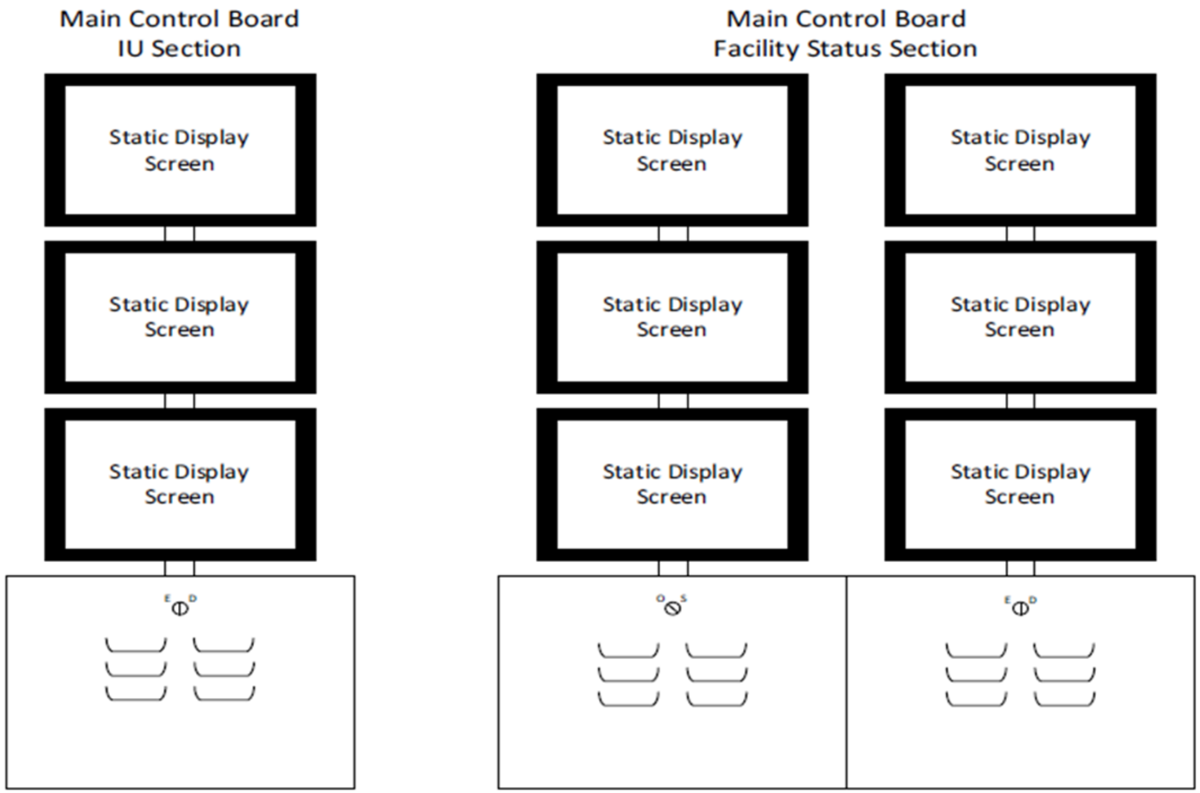
Gateway Communications Architecture

Figure 7-15-1: TRPS and ESFAS Gateway Communications Architecture



Background Information - Main Control Board

Figure 7.6-2 – Main Control Board Sections



PICS REVIEW

Layered Approach to Safety

- Design Criteria – Performance Objectives
  - Provide criterion for achieving reasonable assurance of adequate safety
  - Some are more safety significant than others
- Design Bases – Functions and Values
  - Events Described in other FSAR Chapters
  - Analysis Demonstrates Misbehavior of DB is addressed
  - Variables Monitored & Functions Performed
  - Setpoints and Response Times (Analytic Values)

PICS –Design Criteria in Context

- FSAR Design Criteria for PICS
  - SHINE facility design criteria: 3,6, & 13
  - PICS Criteria: 1-26
  - SHINE facility design criteria for independence of TRPS & ESFAS from PICS are imposed on TRPS & ESFAS
  - SHINE facility design criteria 14, 16, & 18
- Staff evaluated PICS against Design Criteria
  - SHINE facility design criterion 3,6, & 13
  - PICS Criterion 1-10

PICS –Design Criteria in Context

- NRC review focus(given preceding context):
  - PICS equipment failures analyzed to ensure:

    Effects are bounded by events analyzed in safety analysis, see FSAR Section 7.3.2.2.4, “Effects of Control System Operation/Failures”
  - PICS Independent from TRPS/ESFAS
    - Description in FSAR Section 7.3.1.3.11, “Target Solution Vessel Reactivity Protection System and Engineered Safety Features Actuation System”
    - Description in FSAR Section 7.3.2.2.4, “Effects of Control System Operation/Failures”
    - SHINE facility design criteria 14, 16, & 18 (imposed on TRPS & ESFAS)

PICS – Design Bases

- FSAR Section 7.3.1, “System Description”
  - Has subsection for each: IU & RPF
  - Each has subsections for each system controlled, which describes applicable PICS functionality:
    - Variables Monitored and Alarmed
    - Control Functions
    - Interlocks and Permissives

Staff Evaluation of PICS

- Based on its review of the information provided, the NRC staff concludes the design of the PICS meets the applicable design acceptance criteria in Section 7.3 of NUREG-1537, Part 2.
- Based on the information reviewed, the NRC staff concludes that SHINE established the necessary design, fabrication, construction, testing, and performance requirements for the PICS to provide reasonable assurance that the facility be operated without undue risk to the health and safety of the public.

Questions

BACKGROUND

Acronyms

APL	actuation and priority logic (see HIPS TR)
ASAI	application specific action item (see HIPS TR)
BF3	boron trifluoride
BIST	built-in self-test (see HIPS TR)
CAAS	criticality accident alarm system
CAMS	continuous air monitoring system
CCF	common cause failure
CDA	critical digital asset
CM	communication modules (a HIPS module)
COTS	commercial off-the-shelf
CTB	calibration and test bus (see HIPS TR)
EIM	equipment interface module (a HIPS module)
EMI	electromagnetic interference

Acronyms

ESFAS	engineered safety features actuation system
FAT	factory acceptance test
FCR	facility control room
FDCS	facility data and communications system
FPGA	field programmable gate array (see HIPS TR)
HIPS	highly integrated protection system (see HIPS TR)
HVPS	high voltage power supply
HW-SM	hardwired submodule (a HIPS module)
HWM	hardwired module (a HIPS module)
I&C	instrumentation and control
IEEE	Institute of Electrical and Electronic Engineers
IF	irradiation facility

Acronyms

ISG	interim staff guidance
ISM	input submodule (a HIPS module)
IU	irradiation unit
MI-CM	monitoring and indication communication module (see HIPS TR)
MIB	monitoring and indication bus (see HIPS TR)
MWS	maintenance workstation (see HIPS TR)
NDAS	neutron driver assembly system
NFDS	neutron flux detection system
NPSS	normal electrical power supply system
NVM	nonvolatile memory (see HIPS TR)
OOS	out of service(see HIPS TR)
PDC	Principal Design Criteria
PICS	process integrated control system

Acronyms

PLDS	programmable logic design specification
PLRS	programmable logic requirements specification
QA	quality assurance
RAMS	radiation area monitoring system
RCA	radiologically controlled area
RDS	radioactive drain system
RFI	radio-frequency interference
RISM	remote input submodule (a HIPS module)
RVZ1	radiological ventilation zone 1
RVZ1e	radiological ventilation zone 1 exhaust subsystem
RVZ1r	radiological ventilation zone 1 recirculating subsystem
RX	receiver (Figure 7.1-x)
SASS	subcritical assembly support structure
SBM	scheduling and bypass modules (a HIPS module)

Acronyms

SBVM	scheduling, bypass, and voting modules (a HIPS module)
SCAS	subcritical assembly system
SDB1	safety data bus 1 (see HIPS TR)
SDB2	safety data bus 2 (see HIPS TR)
SDB3	safety data bus 3 (see HIPS TR)
SDE	secure development environment (see HIPS TR)
SFM	safety function module (a HIPS module)
SOV	solenoid operated valve
SR	safety-related
SRM	stack release monitor
SRMS	stack release monitoring system
SVM	scheduling and voting module (a HIPS module)
SyRS	system requirements specification

Acronyms

TMR	triple modular redundant
TOGS	TSV off-gas system
TPS	tritium purification system
TR	topical report
TRPS	target solution vessel reactivity protection system
TSPS	target solution preparation system
TSSS	target solution storage system
TSV	target solution vessel
TX	transmitter (Figure 7.1-x)
UPSS	uninterruptible electrical power supply system
V&V	verification & validation
VTS	vacuum transfer system

Advisory Committee on Reactor Safeguards

SHINE Medical Technologies, LLC
Operating License Application

Appendix A - Phased Approach to Startup

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Office of Nuclear Reactor Regulation

October 21, 2022

Regulatory Basis

- Regulatory Requirements
  - 10 CFR 50.34, “Contents of applications; technical information”
  - 10 CFR 50.40, “Common standards”
  - 10 CFR 50.57, “Issuance of operating license”

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

Summary of Application

- On January 27, 2022, SHINE supplemented the FSAR to describe a four-phase approach to startup operations.
- Phased completion is staggered over a few years and planned for completion in 2025.
- In the supplement, SHINE describes the technical impacts and information differences for each chapter of the full-design facility FSAR.
- SHINE identifies equipment isolation points and methods for each phase.
- SHINE FSAR Chapters 4, “Irradiation Unit and Radioisotope Production Facility Description,” 7, “Instrumentation and Control Systems,” 9, “Auxiliary Systems,” and 13, “Accident Analysis,” are most impacted.

Summary of Application (continued)

- Irradiation units (IU) are designed and operated independently (unit specific equipment).
- Tritium Purification System (TPS) consists of three independent trains to support IU operation.
- Except for the iodine and xenon purification/packaging (IXP) system and the radioactive liquid waste isolation (RWLI) selective removal capability, all systems for the Radioisotope Production Facility are installed to support Phase 1 operations.
- Instrumentation and Control Systems are IU specific (TRPS), or inputs are disabled (ESFAS and PICS)

Summary of Application (continued)

- Five new accident sequences were identified, and five existing accident sequences had an increase in likelihood
- New accident sequences
  - Improper target solution routing (Uninstalled IU or IXP)
  - Damage to the TPS train
  - Damage to the process vessel vent system(PVVS)/TOGS interface
  - Backflow of target solution to the IXP
- Likelihood increase
  - Heavy load drop on the TPS
  - Heavy load drop on an operating IU or TOGS cell
  - Heavy load drop on the RLWI enclosure or supercell
  - Fire in the irradiation facility or radioisotope production facility

Staff Evaluation

- The same NRC staff that reviewed the full-design FSAR Chapter reviewed the same chapter in the SHINE Supplement (Phased Approach to Startup)
  - Evaluated the effect on the sufficiency of the SHINE facility description and the design bases, the limits on facility operation, and the safety analysis of the structures, systems, and components (SSCs) and of the facility as a whole as presented in the SHINE FSAR.
  - Reviewed the kinds and quantities of radioactive materials expected to be produced in the operation of the SHINE facility and the means for controlling and limiting radioactive effluents and radiation exposures.
  - Reviewed the methods and sufficiency of system-level isolations for the different phases to ensure safe operation of the facility and to ensure health and safety of the workers and public.

Staff Evaluation (continued)

- The NRC staff audited information supporting the phased approach to startup.

- Initial areas of perceived risk significance for phased approach to startup
  - Human system interfaces/training of operators
  - Disabling/enabling instrumentation and control inputs
  - Increase crane operation with heavy loads during operation
  - Radiological dose to workers completing construction

Phased Startup Operation License Condition

- 10 CFR 50.57(b) requires each operating license issued by the Commission to include appropriate provisions with respect to uncompleted items of construction and such limitations or conditions as are required to ensure that operation during the period of the completion of such items will not endanger public health and safety.

- SHINE provided a phase-specific listing of installation and functional testing activities required to support operation of Phase 2, Phase 3, and Phase 4.

- NRC staff is imposing a license condition to ensure that the operation of the subsequent phases of the SHINE facility will not be commenced until the associated uncompleted items of construction have been completed and that appropriate NRC oversight of the completion of the uncompleted items of construction is maintained.

Phased Startup Operation License Condition (cont.)

License Condition is as follow:

The Licensee shall conduct activities for startup of facility operations in Phases, as described in SHINE Technologies, LLC Application for an Operating License Supplement No. 31, Enclosure 3, Phased Startup Operations Application Supplement, dated September 28, 2022 (ADAMS Accession Nos. ML22271A963 and ML22271A966), as amended. Operation of Phase 2 or of any subsequent Phase shall not commence prior to satisfaction of conditions (a) and (b) below:

a) *No later than 14 days before the planned commencement of operation of Phase 2, and thereafter no later than 14 days before the planned commencement of operation of each subsequent phase, the Licensee shall notify the NRC in writing that all uncompleted items of construction related to that Phase have been completed.*

b) *Prior to the operation of Phase 4, the Licensee shall provide to the NRC in writing, six months after the issuance of this operating license and every six months thereafter, information on the status and schedule for completion of uncompleted items of construction.*

Evaluation Findings and Conclusions

- SHINE described the design of the systems and identified the major features or components affected by the proposed phased approach to startup for the protection of the health and safety of the public.

- The processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other TSs, provide reasonable assurance that the applicant will comply with the regulations in 10 CFR Part 50 and 10 CFR Part 20 and that the health and safety of the public will be protected during the phased approach to startup.

- The issuance of an operating license for the facility would not be inimical to the common defense and security or to the health and safety of the public.

- The NRC staff finds that the descriptions and discussions of SHINE's systems as affected by the phased approach to startup are sufficient and meet the applicable regulatory requirements and guidance and acceptance criteria for the issuance of an operating license.