Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on Reactor Safeguards
Non-Power Production and Utilization
Facilities Subcommittee: Open Session

Docket Number: (n/a)

Location: teleconference

Date: Wednesday, November 4, 2020

Work O rder No.: NRC-1208 Pages 1-63

NEAL R. GROSS AND CO., INC.
Court Reporters and Transcribers
1323 Rhode Island Avenue, N.W.
Washington, D.C. 20005
(202) 234-4433

DISCLAIMER

UNITED STATES NUCLEAR REGULATORY COMMISSION'S ADVISORY COMMITTEE ON REACTOR SAFEGUARDS

The contents of this transcript of the proceeding of the United States Nuclear Regulatory Commission Advisory Committee on Reactor Safeguards, as reported herein, is a record of the discussions recorded at the meeting.

This transcript has not been reviewed, corrected, and edited, and it may contain inaccuracies.

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS

(ACRS)

+ + + + +

NON-POWER PRODUCTION AND UTILIZATION FACILITIES

SUBCOMMITTEE

+ + + + +

WEDNESDAY

NOVEMBER 4, 2020

+ + + + +

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

COMMITTEE MEMBERS:

RONALD G. BALLINGER, Chairman

DENNIS BLEY, Member

CHARLES H. BROWN, JR. Member

VESNA B. DIMITRIJEVIC, Member

WALTER L. KIRCHNER, Member

JOSE MARCH-LEUBA, Chairman

DAVID A. PETTI, Member

JOY L. REMPE, Member

MATTHEW W. SUNSERI, Member

ACRS CONSULTANT:

STEPHEN SCHULTZ

DESIGNATED FEDERAL OFFICIAL:

CHRISTOPHER BROWN

DEREK WIDMAYER

ALSO PRESENT:

STEVEN LYNCH, NRR

TRACY RADEL, SHINE Medical Technologies

JIM COSTEDIO, SHINE Medical Technologies

JON DELVENTHAL, SHINE Medical Technologies

CATHERINE KOLB, SHINE Medical Technologies

JON OLVERA, SHINE Medical Technologies

JEFFREY BARTELME, SHINE Medical Technologies

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

P R O C E E D I N G S

(9:30 a.m.)

CHAIRMAN BALLINGER: This meeting will now come to order. This is a meeting of the SHINE, of the Advisory Committee on Reactor Safeguards, the SHINE NPUF Subcommittee.

I'm Ron Ballinger, Chairman of the SHINE Subcommittee. We have a quorum, so there's no need to call the attendance, I don't think. Christopher Brown and Derek Widmayer are the Designated Federal Officials for this meeting. I think the Court Reporter's on, yes.

The purpose of today's meeting is for the subcommittee to receive a briefing from SHINE Medical Technologies, LLC, which will consist of an overview of SHINE medical isotope production of the facility. Also, we'll hear from the staff on their approach to review the SHINE operating license application.

The ACRS was established by statute and discovered by the Federal Advisory Committee Act, FACA. The NRC implements FACA in accordance with its regulations found in Title 10 of the Code of Federal Regulations, Part 7.

The committee can only speak through its published letter reports. We hold meetings to gather

information and perform preparatory work that will support our deliberations at a full committee meeting.

The rules for participation in all ACRS meetings were announced in the Federal Register on June 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 agenda for this meeting is posted there. Portions of this meeting will be closed to protect proprietary information pursuance to 5 U.S.C. 552b(c)(4).

For the open part of this meeting we have -- we'll also have set aside five minutes for comments from members of the public contending or listening to this meeting. We've had no request for making a statement to the subcommittee.

A transcript of the meeting is being kept and will be available on our website for the open portion of the meeting. Therefore, we've requested participants in this meeting to first identify themselves and speak with sufficient clarity and volume so that they can be readily heard.

Please pause from time to time to allow

members to ask questions. Also, for presenters, because of the video nature of this thing, this meeting, please sometimes let us know what slide number you're on.

We have a bridge-line established for the public to listen in to the meeting. To minimize disturbance, the public line will be kept in a listening mode only. Public line will be terminated during the closed session.

Okay, okay. Note that we have scheduled the next subcommittee meeting for January 13th, 2021. Per our many discussions, we are asking for SERs that have been completed before the December 13th due date.

Also, I'll probably say this in closing remarks, but in case I forget, we will have a meeting to discuss the review format for SHINE in December at our P&P meeting.

So it's very important that by that time we have available feedback from members related to the format that we might be -- that we'll be agreeing to.

So having said that, I think we need to turn to, I guess, Steve Lynch, who'll give some staff opening remarks. Steve, are you there?

MR. LYNCH: Yes, I am here. Thank you.

So for everyone, my name is Steve Lynch.

I'm a Senior Project Manager in the Non-Power Production and Utilization Facility licensing branch in the office of Nuclear Reactor Regulation at the NRC. I am the lead project manager for the review of the SHINE operating license application.

I appreciate the opportunity that the members are providing both SHINE and the NRC staff this morning to provide an introduction to this review. It is important not only to our agency, but also to providing medical care to citizens of the United States and around the world for the production of molybdenum-99 and other radioisotopes.

Our goal for this meeting this morning is to familiarize ACRS with the NRC staff's approach to reviewing the SHINE operating license application, recognizing some of the unique technical and licensing considerations associated, a subcritical operating assembly, and production facility to be licensed under 10 C.F.R. Part 50.

So we hope that coming out of this meeting we can further the conversation on the strategy for engaging in additional technical subcommittee meetings to --and make sure that we are able to get the ACRS members the information that they need in order to conduct their independent review of the application,

and the staff's safety evaluation.

So thank you for your time today and I'll look forward to presenting later this morning.

CHAIRMAN BALLINGER: Thanks, Steve. So now, I guess we turn it over to the SHINE folks. And, Tracy, are you on?

MR. COSTEDIO: Yes. Good morning, this is Jim Costedio. I'm the --

CHAIRMAN BALLINGER: Whoops, you're not Tracy. Sorry.

MR. COSTEDIO: No, I'm not. I wanted to open. I'm the vice president of regulatory affairs and quality for SHINE. And we want to thank the ACRS subcommittee members for hosting us virtually today. We're very excited to be here. It's been a long time since we last met, I think October of 2015. So we have made significant progress as to the construction permit phase.

Today we're going to discuss design refinements that have resulted in some changes to the facility. All these changes were made to improve safety, constructability, and operation of the facility.

We're also going to discuss our construction status, technological approach, safety

philosophy, and give a process overview.

So we look forward to, and we'll embrace the feedback from the ACRS subcommittee today. So we have a lot to cover. Thanks again, and I'll turn it over to Tracy Radel, our VP of engineering.

MS. RADEL: Thanks, Jim. I echo Jim's remarks in that we are very excited to present the overview today of the SHINE design, and we look forward to the questions, comments, and conversation that will come out of this.

So let's get started. The stuff we'll cover in the open session today includes the site plan, the status of our construction process overview, technological approach, and our safety philosophy.

SHINE's site is located in Janesville, Wisconsin. You can see it here in this overhead view outlined in red. As we zoom in you can see the site plan shows where the production facility is relative to the different support and outbuildings for the facility.

Here's a rendering of the site. So you can see what we expect it to look like, or about what we expect it to look like when the construction is finished.

We're currently undergoing construction

on the main production facility, the building at the center there. The construction status, here's some images of recent construction status. So rebar, there's a significant amount of rebar in the facility.

You can see there this is the rebar for the second lift on the east wall. You can also see it in the picture here at the bottom. Here's a overhead view from the crane. You can see the layout of the facility, the different subgrade faults here.

There's a significant number of embedded items. Conduits, penetrations, pipe sleeves, some of those shown here. And then in the upper right corner here is a view down the irradiation unit cells prior to the dividing walls being placed.

MEMBER BLEY: Tracy?

MS. RADEL: Yes?

MEMBER BLEY: This is Dennis Bley. One question on this slide and then I'd like to go back two. In seeing the conduit here, I don't remember, are all your cables going to be in conduit? Or some in cable trays?

MS. RADEL: There are cable trays as well as conduit.

MEMBER BLEY: Okay.

MS. RADEL: Basically.

MEMBER BLEY: And back two slides.

MS. RADEL: Okay.

MEMBER BLEY: I'm sorry, one more. I didn't remember. I remembered that you were very close to this small airport. I didn't remember that you were kind of almost lined up with that southwest to northeast runway. That's always been your site thought, right? In that same location?

MS. RADEL: Yes. It's the same site as we had with the construction permit.

MEMBER BLEY: Okay. Thank you.

MS. RADEL: Okay. And moving on to the process overview. The process begins with the preparation of target solution. We take uranium oxide and dissolve in sulfuric acid and peroxide, adjust for pH and uranium concentration. That's the put into the process into a hold tank.

There are eight hold tanks. One for each of the irradiation units. It is then loaded into the irradiation unit using a 1/M approach. Once the solution has been filled to the proper level, which is nominally 5% by volume below predicted critical, the irradiation unit is isolated, and irradiation begins.

Irradiation is for approximately five and

a half days. And then following the five and a half days of irradiation, it would be gravity drained to a favorable geometry. Dump tank at the base of the subcritical assembly where it would be allowed to cool and a short decay period for short-lived fission products.

Following that, it is transferred over to the supercell where the molybdenum is extracted, and the target solution would then flow back to the target solution hold tanks.

The molybdenum would go through the different processes within the supercell, which include purification, QC checks, and then packaging before being shipped out.

In the process of extraction and purification, there are liquid wastes generated. That liquid waste would be immobilized through the solidification process.

Any questions on that?

MEMBER PETTI: Yes, I had a question on the tritium waste. The tritium is going to permeate and get into your atmosphere, and I assume you're going to be cleaning up the atmosphere. And what's the ultimate path for the tritium?

MS. RADEL: So the tritium purification

system, we capture that tritium and then purify it using that TCAP system. There's additional slides in the closed session and that process.

And to be clear, the tritium system would be within the tritium target chamber of the --at the center of the subcritical assembly. It wouldn't be in with the uranyl sulfate solution process flow here. So there's quite a few more details in the closed session about how the tritium purification system works.

MEMBER PETTI: Okay, thanks. I'll wait.

MS. RADEL: Okay.

MEMBER KIRCHNER: Tracy, this Walt Kirchner. And then after the target solution, that's LEU, right?

MS. RADEL: Yes. LEU.

MEMBER KIRCHNER: Thank you.

MEMBER PETTI: And so just a question, compared to the traditional way to make moly-99 with ATU, is this high-specific activity or low-specific activity moly-99 in terms of the separation? Or is it like medium?

MS. RADEL: It's high specific activity.

MEMBER PETTI: It still is? Okay.

MS. RADEL: Yes.

MEMBER PETTI: Thanks.

MS. RADEL: And moving on to the technological approach. So one key item is that these are small systems; so the license limit power of each of the irradiation units is 125 kilowatts. This is hundreds of times less power than isotope production reactors currently being used.

This leads to a much lower source term, which helps ensure the safety of the public and workforce. It also leads to lower decay heat. We're at less than a kilowatt within five hours.

And the solution is passively cooled by the light water pool following irradiation. It also minimized the waste generated in the isotope production because the majority of fissions that are occurring within the system are occurring to produce recoverable moly.

So in the current system, the reactors have a significant amount of fission occurring within the fuel that is not directly going to generating moly for isotope production.

We use a low-enriched uranium reusable target. The ability to reuse the target efficiently greatly reduces waste.

The use of a uranium target means that it's

compatible with the current supply chain producing that high-specific activity moly that the industry is used to. And the use of low-enriched uranium eliminates the need for highly enriched uranium.

It's driven by a low-energy electrostatic accelerator. This means that when the accelerator is turned off that the fission essentially terminates shortly after. And this a key design feature of the system.

The multiple units, multiple irradiation units, and multiple processing trains provide operational flexibility and scalability. So we have eight individual irradiation units, and then we have three independent processing lines.

And each of the eight irradiation units can be processed through multiple processing lines.

MEMBER BLEY: Tracy, maybe you're going to talk about this in the closed session, I'm not sure, but last time around the way designed this you were running very close to critical. Have you changed your plans for operating regime? Or is going to be about the same as we saw before?

MS. RADEL: It's about the same as before. So the 5% by volume below critical, and there is more on that in closed session.

MEMBER BLEY: Thank you.

MS. RADEL: Yes. Part of the safety philosophy, the systems are at low pressure slightly so the atmospheric low temperature and have a low decay heat. And this means that there's minimal stored energy there to drive any type of release if it were to occur.

The independence of the eight irradiation units limits common cause failures, it limits the source terminates available. The units do not require any operator actions to mitigate the consequences of an accident.

And in the event of an on-site condition, the TSV reactivity protection system would initiate a trip. That trip would open two completely independent safety related TSV dump valves, and the target solution would gravity drain to the TSV dump tank, which is safe for all uranium concentrations.

The hydrogen concentration is maintained below the lower flammability limit by the off-gas system. Following the battery run time, the entire plant is passively safe. So the target solution was cooled by the pool it's sitting in. And the pool temperature would not rise more than 13 degrees over 90 days without any active cooling.

The nitrogen purge system provides hydrogen control. It provides a sweep gas through the system to purge the hydrogen.

MEMBER PETTI: Just a question on the accelerators and the assumptions of your design. There's a certain level of fusion that occurs, is there a margin in terms of what if you get better fusion than you think and so you end up with more neutrons and, you know, going into the uranium. Is there a margin there?

MS. RADEL: Yes, so the power is monitored through the detectors, and they would catch any kind of increase in production of the drivers, which would drive, you know, power up within the subcritical assembly.

There's not a mechanism that would lead to drastically increased production by the neutron drivers beyond what they've been testing or show to be capable of. And we can talk more in details of that in the closed session.

MEMBER PETTI: Okay.

MR. RADEL: Okay. Any other questions? This is the last slide for open session.

CHAIRMAN BALLINGER: No questions? We have made a potentially fatal error in that we're ahead

of schedule. I think at this point we need to make sure the public line. I'm assuming it is. So I think it is, yes, yes.

So are there any members of the public that would like to make a comment?

MALE PARTICIPANT: The line is open for comment.

CHAIRMAN BALLINGER: Thank you. If so, please state your name and make your comment.

I'm hearing none. I think we can close the public line.

We need to now transfer to the closed session. Let me go offline -- transfer to the closed session. So we need to leave this session and then rejoin in the closed session. So we should take about a ten-minute break. It's 9:52 so at just a little bit after 10, say 10:05, to round things up.

We'll rejoin in the closed session. So unless there are other member comments, we'll now leave this session, and we'll see you in the closed session.

(Whereupon, the above-entitled matter went off the record at 9:52 a.m. and resumed at 11:55 a.m.)

CHAIRMAN BALLINGER: Okay. It's 11:55. We're back in session and I think Steve Lynch, you're up.

MR. LYNCH: Yes. Thank you very much. Thankfully my Teams just cooperated, and I am back online. Just confirm for me when you can see my presentation slides that I'm sharing.

CHAIRMAN BALLINGER: I could see your slides but it's not full screen.

MR. LYNCH: Okay. Let's do that right now. Okay. Now I can take of this.

CHAIRMAN BALLINGER: Looking good.

MR. LYNCH: Okay. Thank you everyone for your time this morning and afternoon. I will try to make sure I pay attention to the time, but if we need to speed up feel free to let me know and we can adjust the pace.

To compliment SHINE's presentation regarding the overview of their technology, what I'd like to present today as a first step is our engagement with the ACRS members on the SHINE Medical Technologies operating license application review is to provide some background and also the test and methodology with the NRC staff needed to review the SHINE operating license application.

And hopefully what we can do coming out of this meeting is continue our conversation on how to best approach the technical subcommittee meetings

that are to follow this licensing meeting that we have having so that we can one, make sure that we're providing the information that is most useful to the ACRS members, and also make sure that we are streamlining our process to the extent that we are presenting information in a way that is focusing on what's most safety significant for this application, and providing appropriate context for the discussions that we have.

So the first couple slides I'm going to go through some background on our NRC staff involvement in these reviews, some of the drivers that come from applicable statutes, coordination with other federal agencies, and also drivers that we have from external to external to the government.

So when it comes to medical radioisotopes, and in particular, the production of molybdenum-99 that SHINE is proposing to produce, there is a significant effort from the international community, and in line with U.S. policy, to establish a domestically available and reliable supply of this medical radioisotope without using highly enriched uranium.

SHINE discussed earlier this morning they are using an LEU solution in order to produce molybdenum-99. As you may know, 6% of the fission products of U-235 are molybdenum-99. And when you have

those pure molybdenum-99 fission products, you do end up with high-specific activity technetium-99 metastable because you don't have other molybdenum isotopes that could reduce the specific activity that then is provided as the radiopharmaceutical for diagnostic or therapeutic purposes.

As far as the NRC is concerned, we do look at initial license applications and license amendment requests for a variety of different types of licensing actions that involving manufacturing of targets for irradiation, the actual technologies that are used for irradiation, and the processing of those targets once they've been irradiated.

For the purposes of the office of Nuclear Reactor Regularization, our focus is primarily on those utilization and production facilities that are covered under 10 C.F.R. Part 50, which is our framework that we use primarily for reviewing nuclear power reactor and non-power reactor facilities.

In terms of what our drivers are outside of our regulations and the applications that come to us, we do have coordination with other federal agencies for reviews related to molybdenum-99. In particular, there is the American Medical Isotopes Production Act that does provide the coordination between the NRC's

staff and the National Nuclear Security Administration.

There are two key provisions of this act that are applicable to the NRC. One of those is on coordination of the National Environmental Policy Act of use, or environmental disuse.

Basically, the provision there is for those actions where both the NSSA and the NRC have federal jurisdiction should we need to coordinate on those NEPA reviews. So we are preparing a joint supplemental environmental impact statement to support the review of the operating license application with NSSA.

And then the other piece of this is a uranium lease and take-back program. The act provided that DOE NSSA establish this uranium lease and take-back program in particular so that if there is waste that does not have a commercial disposition pathway that the Department of Energy, through an agreement with an applicant, would be responsible for disposing of that waste.

And that program is established and available to all applicants through SHINE. Also, there is coordination with the Department of Homeland Security, and this has to do with site vulnerability assessments that are performed for any new utilization facility constructed in the United States.

This vulnerability assessment was performed at the construction permit stage of the SHINE review, and the results of that were taken into consideration by both the NRC staff and the applicant in the review of the application and preparation of the application.

And then the other act that I would like to highlight here that is applicable to the work that we are doing is the Nuclear Energy Innovation and Modernization Act.

Among the many provisions of this act, one of the items that is applicable to our review of the SHINE operating license application is the establishment of review periods, in particular, from an initial licensing application setting a generic review schedule of three years is provided for the NRC staff to establish.

As I go on, I do want to just from an administrative point of view, I am hearing some pop-ups and potential comments coming up. Unsure if they're being directed to me or not. I just want to say that while I've got my presentation in full screen mode, I can't see any text messages that may be sent via Teams. So if someone, particularly the ACRS members, if you have something you'd like for me to address, please

speak up.

CHAIRMAN BALLINGER: This is Ron. I don't think we use that method.

MR. LYNCH: Okay.

CHAIRMAN BALLINGER: So you'll hear voices.

MR. LYNCH: Okay. No problem. I just wanted to make sure that I'm not missing anything because I can't see it.

Okay. Now, to get back into a little bit more of the policy work that the NRC staff has engaged in to prepare for the review of non-power production or utilization facility reviews and the SHINE review, there's a couple rulemakings that I do want to highlight that are of particular relevance and importance to the work that we're doing.

One of these is the non-power production or utilization facility, or NPUF, license renewal final rule that was submitted to the commission for consideration in June of 2019.

While the focus of this rule was looking at eliminating license renewal terms for certain NPUF facilities, one of the other provisions of this rule that will have a direct impact on our licensing of facilities like SHINE is the establishment of an

accident dose criterion, which does not currently exist in our regulations for a facility like SHINE.

So what that would do is establish an accident dose criterion of one rem at the site boundary for facilities like SHINE.

Currently, in absence of having a regulatory requirement for accident dose criterion for non-power production and utilization facilities, the NRC staff has conservatively accepted proposals from currently licensed non-power reactors 5 and medical radioisotope facilities, like SHINE, to previously use 100 millirem as their accident dose criteria, which is consistent with the normal annual release limits in 10 C.F.R. Part 20.

So expanding to the one rem dose limit is consist with the EPA PAGs. And I believe through the regulatory audit we had with SHINE on their accident analysis, SHINE is planning on adopting that accident dose criterion of one rem for their facility.

And then the other rulemaking that is important to the work that we're doing with SHINE that kind of guides the regulatory review that we are doing was the definition of utilization facility direct final rule that was published in the Federal Register in October of 2014.

The significance of this rulemaking was expanding the definition of utilization facility in 10 C.F.R 50.2 to include, by docket, a SHINE accelerator driven subcritical operating assemblies.

So this was a rule of particular applicability, meaning that it was limited to a single entity. So in order to ensure that we did not have unintended consequences by impacting other subcritical facilities, this rulemaking was limited to just the SHINE technology.

And the practical implication of this rulemaking is providing that the SHINE subcritical operating assemblies would be licensed as utilization facilities. So they would follow a similar licensing path to non-power reactors that are licensed by the NRC.

Now I touched on this briefly in one of my earlier slides, but I did want to highlight the scope of technologies that are covered under radioisotope production processes that the NRC looks at. And this really breaks down into four main categories.

We've got target manufacturing, target irradiation, target processing, and then the medical use of byproduct material. For the SHINE application, what we are focused on is the target irradiation using

subcritical operating assemblies, and then the target processing that utilizes SHINE's hot cell facility to process the irradiated low-enriched uranium solution to extract the molybdenum-99.

The target manufacturing we have seen for other applications for the manufacturing of solid LEU targets that would be placed in reactors for other facilities or irradiation. And then the medical use of byproduct material really gets down to the generators that actually are doing the extraction of the technetium-99m from the molybdenum-99, which is not part of the SHINE proposal.

And when we're -- you know, one of the things that drove our rulemaking to classify SHINE's subcritical operating assemblies as utilization facilities really came down to what were the safety considerations for that facility.

When we were looking at this there was the initial where the question came up because in order to be a utilization facility under the NRC's traditional regulatory framework, a facility would need to be a nuclear reactor, meaning that it is capable of a self-sustaining chain reaction or having that criticality.

Being a subcritical facility, SHINE did

not meet that definition of a nuclear reactor. However, due to the limited margin or subcriticality that SHINE has, there were many safety considerations that made more sense to look at the SHINE subcritical operating assembly more similarly to how we would evaluate an aqueous simultaneous reactor, including removal of fission heat, aheat generation, generation of fission gasses, and also looking at the potential accident scenarios.

That being said, with the SHINE hot cell facility there are other technical considerations that fall outside of the normal scope of what we would look at for a reactor technology.

And for SHINE in particular, this has to do with some of the criticality considerations for the hot cell facility. Making sure that there is an approved margin of subcriticality in the hot cell facility, and also making sure that SHINE's criticality safety program is applied consistently throughout the facility in all of those areas except for the target solution vessel where the goal is to have that minimum margin of subcriticality.

And then, also the importance is looking at some of the chemical hazards associated with license material that are present in the facility due to the

processing of the irradiated targets that we've shown.

So to kind of bring all of this together, our organization, the Division of Advanced Reactors of Non-Power Production of Utilization Facilities, does have the primary responsibility for leading the project management and reviews of non-power production of utilization facilities, including the medical radioisotope facilities. And this includes looking at non-power reactor technologies, subcritical operating assemblies, and production facilities.

The SHINE facility is going to be licensed as a commercial facility under Section 103 of the Atomic Energy Act. And this does contribute some slight differences in how we look at their facility versus how we would review a research or test reactor.

And mainly this comes down to the implementation of the minimum regulation provision of the Atomic Energy Act that is afforded to research and test reactors licensed under Section 104c.

So as a commercial facility, SHINE does not have that minimum regulation provision applicable to them. That being said, we are tailoring our review based on the safety significance of the facility to ensure that our resources and reviews are focused on those safety related structures, systems, and

components that are necessary to protect the public health and safety.

So given the different types of technologies that we're looking at with SHINE, we are relying on the technical expertise from organizations throughout the NRC outside of NRR.

And, in particular, we are looking to the office of Nuclear Security and Incident Response to help with our reviews of emergency planning and physical security.

We also are looking to our office of Nuclear and Material Safety and Safeguards to help with looking at the material component accounting program, support and accident analysis review, chemical safety, and criticality safety, which are expertise areas that we do not have in NRR to complete this review.

Now a little bit of background on the SHINE application itself. Previously we did receive a two-part instruction permit application in 2013 for the SHINE facility that consisted primarily of an environmental report and preliminary report.

As you heard from SHINE, the basic process involves irradiating and low-enriched uranium target solution in its irradiation facility consisting of eight irradiation units, and then processing that

irradiated target solution in the radioisotope production facility consisting of the hot cells.

Following our review of this application, a construction permit was issued in February of 2016 and SHINE commenced construction of its facility in September of 2019 in Janesville, Wisconsin.

I do want to just clarify on this date for commencing construction. This is what the NRC staff considers construction under our definitions in 10 C.F.R 50.10. My understanding is that SHINE did have other site preparation work that had to be done prior to that September 3rd date.

Now this touches a little bit on the items that were highlighted in the ACRS member letter I follow that supported issuance of the construction permit and looking at what was covered in that appendix A of the staff safety evaluation report, which covered items that would need follow-up past the issuance of the construction permit.

There were several items contained in that appendix. Among those include these periodic reports on permit conditions were addressed. We also had technical areas where SHINE had made regulatory commitments to provide information in the operating license application for the NRC staff review to make

an ultimate safety finding.

So before I get into the particulars of these permit conditions, what I'll highlight when it comes to how the staff is conducting its review of this Part 50 application, at the construction permit stage, the NRC staff did not make any ultimate safety findings that were final.

And because of the nature of the SHINE design that was going to continue to evolve as it went from a preliminary design to a final design. And I believe that's highlighted with the design changes that SHINE presented at the beginning of today's meeting.

So what this means is while the NRC staff conducted a review of all of the available information at the construction permit stage as described in that appendix A, and in the regulations in 10 C.F.R. 50.35, there is an expectation that information that had not previously been reviewed or considered would be made available to the NRC staff in order to make its safety findings and ultimately issue an operating license application.

So because the --

RECORDING: Mute on.

MR. LYNCH: I'm sorry, one sec. Okay. That was not my mute, so I am still here. My apologies.

Let me get back to full screen. I just wanted to make sure that I was not inadvertently muted.

So my apologies. So essentially what I would like to highlight here is going from the construction permit review to the operating license application review, the NRC staff is not so much conducting a delta review looking at those differences, so much as we are potentially taking a fresh review of the application.

So in all areas that we looked at during the construction permit application review, we are looking at again, based on the updated and complete design information provided in the SHINE final safety analysis report.

That being said, the NRC staff is informing its review of this final information by looking back to the items highlighted in appendix A for those areas where SHINE had made commitments to providing updated -- and to the extent that design changes have made certain commitments no longer applicable and necessary, the NRC staff will make note of that as part of our ultimate evaluation findings.

And, you know, our intent is also as we prepare our safety evaluation report, input to address these areas in appendix A to make sure that, yes, the

NRC staff did make a standalone review of the FSAR information to the extent that they were relevant and valid.

And the commitments made by SHINE at the construction permit stage that are also applicable and necessary for us to make our necessary evaluation findings based on our standard review plan and the regulatory findings in 10 C.F.R., we will make sure that all of that is addressed and presented to the ACRS members as we go through our technical presentations.

With respect to these particular periodic reports, recognizing that SHINE had a fair amount of development work to go when the construction permit was issued in the areas of its criticality accident alarm system, nuclear criticality safety evaluations, and additional shielding design application, the NRC staff did have these conditions on the permit for SHINE to provide reports to us that would provide updates on how they were developing the information.

The primary goal in having this information was to support construction inspection activities should they have to be done prior to the submission of the operating license application, and that would contain the complete technical -- to make sure that our inspectors would have all of the information they

needed in order to conduct their inspections.

Now based on how the timing of all of this worked out, while we've had these periodic reports submitted by SHINE, SHINE submitted its operating license application in July of 2019, and our first construction inspection activities began in December of 2019 following SHINE's commencement of construction in September of 2019.

So the inspection information that we are using is based on the FSAR and supporting materials that SHINE provides to NRC staff in its electronic reading as necessary to support specific inspection activities.

So while SHINE provided this information, the current information that we are using support our review and inspection activities is based on the end test for that.

So with this, I think I can go through the next few slides fairly quickly as we've covered most of this already. The main point here that I want to emphasize is that the SHINE irradiation facility, which consists of the eight subcritical irradiation units is going to be licensed and reviewed against the requirements in 10 C.F.R. Part 50, which mostly mirror those requirements used to evaluate applications for

non-power reactors.

And then for the radioisotope production facility, this is also evaluated under the NRC staff regulations and guidance under Part 50 for a production facility.

As you may be familiar, there are three different types of production facilities described in the NRC's regulations. This includes those production reactors used for the production of special nuclear material, like the Hanford reactor, new processing facility, like the West Valley facility, and then the third type of production facility is for those facilities used for the separation of byproduct material from irradiated special nuclear material.

And that's what all of the medical radioisotope facilities have proposed that are using low-enriched uranium and having separation processes.

Now the important distinction here, and when we're determining what the appropriate licensing process is to apply to these facilities, we are looking at what is the bath size, so how much special nuclear material is going to be processed at one time.

I our regulations there is a threshold drawn at 100 rams. So if a facility is processing greater than 100 rams of special nuclear material at

one time, that is what pushes them into the Part 50 requirement for a production facility.

If a facility were to stay below that 100 ram threshold, they would be licensed under 10 C.F.R. Part 70 for similar to existing fuel cycle facilities.

That being said, while the SHINE production facility is being licensed under 10 C.F.R Part 50, as I mentioned earlier, we are relying on technical staff from our office of NMSS to support us in our review of certain accident sequences, criticality safety, and chemical safety to the extent that there are technical similarities between the production facility and fuel cycle facilities.

So in addition to the Part 50 license that SHINE has requested, there would be provisions under this license ensuring that SHINE is meeting applicable proximity requirements for the possession and use of special nuclear material, and for the possession and use of source material under Part 70 and Part 40, respectively.

Now I'll transition to a little bit more talking about the specifics of the NRC staff review of the operating license application that was submitted by SHINE back in July of 2019.

So following that submission of the

application back in July, the NRC staff performed a 60-day acceptance review of the application and accepted the application for review in October of 2019.

Based on this accepted review, the NRC staff did highlight certain technical areas that were going to require focused attention and engagement between the NRC staff and SHINE in order to make sure that we've reached a technical and licensing resolution.

The two main topics identified were instrumentation and control systems, and the accident analysis and methodology. The reasoning for highlighting these areas, we recognize that for SHINE's instrumentation and control systems they are utilizing the Rock Creek platform that NuScale has used for its I&C systems.

And in particular, our staff wants to make sure that from the safety evaluation prepared for the NuScale system that appropriate consideration has been given to the 65 application specific items in our review of the application, and making sure that we are consistent in our review methodologies of the SHINE I&C systems and of recent digital upgrades we've had for research reactors.

MEMBER BROWN: Can I ask a question, Steve?

MR. LYNCH: Sure. Absolutely.

MEMBER BROWN: When you talk about utilizing the NuScale systems, does that mean -- and you talked about the Rock Creek, the most reasonable would be -- I may be on the wrong branch with this, but their reactor protection system and their ESFAS system, whichever one, however we want to call it here, utilize field programmable gate arrays as opposed to microprocessors in the their processing. Is that what you're talking about? Because we've seen nothing relative to what they look like now.

MR. LYNCH: Sure. So at a high level, what I will say SHINE does have an ESFAS system in the --

RECORDING: Mute on.

MR. LYNCH: In the Rock Creek platform that has been customized for SHINE. With respect to the use of the microbe processors, I think I would refer to SHINE to answer what they are specifically using in that.

But it is a -- but what I will say is that it isn't an exact replica of the NuScale platform. It has been customized for SHINE.

MEMBER BROWN: Well, customization is fine. I understand there's a big difference between an operating plant and this facility set up. And if

that difference was, you know, evident in our earlier review, I was just wondering if when you say it was consistent, the FPGA approach that they used is not a software-based driven system.

It was almost like hard-wired stuff once you program the FPGAs. So that's all I was interested in when you were talking about the details. Because we didn't get that detail before.

MS. RADEL: Yes. So this is Tracy Radel with SHINE again. We are using the HIPS platform highly integrated protection --

MEMBER BROWN: Okay.

MS. RADEL: --system from Rock Creek and it is using those field programable gate arrays, the FPGAs.

MEMBER BROWN: Okay. Excellent. That's just what -- I wanted to make sure I -- I didn't refer to it as Rock Creek. I always thought of it as HIPS. So you said the magic words.

MS. RADEL: Yes.

MEMBER BROWN: Okay. Thank you very much.

MR. LYNCH: Thank you. And then the other focus area for the NRC staff has been the accident analysis performed by SHINE.

We've had some successful audits.

Actually, both of these technical areas that has furthered our review, in particular, with the accident analysis methodologies.

One of the outcomes of our recent audit with SHINE that I began in August of this year and concluded a few weeks ago in October was reevaluating how SHINE was performing its accident analysis to make sure that a complete set of design basis accidents were presented in the application, and also to ensure that we had a mutual understanding of how SHINE was using its SHINE safety analysis that is an undocketed report that SHINE discussed that covered additional accident sequences and controls that had been identified for different accident categories, and making sure that we had connection between the SSA, SHINE's design basis accidents, and then ultimately what is being treated as a founding accident scenarios against a one rem criteria.

So this here, we do have a set up request for additional information on the accident analysis that are prepared. They're in concurrence right now and ready to be issued this week. And we are expecting to have responses for requests for additional information, and an updated safety, final safety analysis report on this information submitted in about

30 days.

So by early December we expect to have updated information on the accident analysis and methodologies, and have essentially this portion of the review resolved. So that's --

MEMBER BLEY: Steve?

MR. LYNCH: Yes?

MEMBER BLEY: It's Dennis Bley. I have two questions.

MR. LYNCH: Yes.

MEMBER BLEY: One you jumped at me as you said this, the other one I thought earlier. When you guys have been doing your review, have you had access to or in the FSAR anywhere, I haven't had a chance to look through new documents, the process flow sheets for the chemical side of the plant.

The other question is I think I just heard you say the safety analysis document that's undocketed is -- tell us more about that.

MR. LYNCH: Sure. So in order to support our reviews of the application, SHINE has established an electronic review portal to upload reference materials to include different flow sheets and tables and calculations and procedures and analyses that support the docketed material in the FSAR.

And they have provided those in areas of their accident analysis to include criticality safety and chemical safety. And when it comes to this SSA, so this is not information that the NRC staff would typically expect to be docketed.

To provide a little bit of background, this SSA previously was referred to as SHINE's integrated safety analysis, or an ISA, that -- and what this represents is a methodology that SHINE used to ensure that they were identifying all of the potential accident sequences and initiating events at the facility, be able to root them, identify the most limiting event within those that becomes a design-basis accident, and also identify the necessary controls for that particular accident sequence.

Now, for the --

MEMBER BLEY: So you're -- or --

MR. LYNCH: Sorry --

MEMBER BLEY: Or maybe the SHINE folk, from our previous discussion, my understanding was that that information Steve just described would also be accessible to the members of the ACRS. Is that correct?

MR. LYNCH: So following the October 22nd meeting, I have had some discussions with SHINE about setting up a custom portal for the ACRS members to review

information. And one of the documents that we highlighted that would most likely be of high interest and value to the members in their review was this document.

So following this meeting, what would I like to do is start working with SHINE on getting this portal up and running and start populating some of these documents that are most relevant and of interest to the members to help to support your review of the application.

MEMBER BLEY: Okay. Thanks. That's really important. Now, you didn't get to the process flow sheets. Sorry I cut you off. Go ahead.

MR. LYNCH: Oh, well, I guess what I was saying is with the -- so when it comes to our review of the information that's in the SSA, some of the requests for additional information, what's important to us in terms of docketed materials is making sure that SHINE has a sufficient description of the methodology.

So what we want is, while we don't need them to docket the SSA in its entirety, we want to make sure that in the FSAR they describe what their process was and what makes it acceptable so that based on our review of that material we still have something in the

FSAR to say yes, this methodology is acceptable and can be used going forward.

Should there be design changes at the facility, the expectation is that SHINE will still perform a 50/59 analysis to determine if a license amendment is necessary to submit to the NRC staff.

And as part of either looking at a license amendment or design changes that -- so let me step back. If it's a license amendment the NRC staff could request to look at the SSA as it's been updated to reflect that amendment to ensure that it's being maintained.

And then should there be design changes that screen out and do not require an amendment, hearing inspection activities, NRC inspectors could look at that SSA to ensure that it's being kept up to date with changes of the facility.

For particular flow sheets I would need to confirm with you that we had our reviewer look at that information related to chemical safety. We did request that SHINE did provide some documents in its electronic reading room on chemical safety and I can confirm with our reviewer what he had looked at.

But we do have a chemical safety RAI that was developed to complete our review and make sure we have what we need on that.

MEMBER BLEY: Okay. I was hoping that would end up being up on that portal when we looked. My past experience with chemical processing plant safety is if you don't -- if the key information you need to be able to really look at safety is in those sheets.

MR. LYNCH: What I've done, though, is I've made a note and we can work with SHINE on getting that information for you.

MEMBER REMPE: Can you give us an idea of the schedule of when you'll have this portal up and running? Or at least a list of documents that would be included in it?

MR. LYNCH: Sure. So some of us all need to coordinate with SHINE on what it'll take to get this updated. So I could talk to SHINE about their schedule for that and I think as we're talking today I'm making notes on what some of these documents are that are key.

Because one of the things that we want to make sure is that, and I can let SHINE speak to this as well since these are their documents, is that, you know, the desire is to make sure that we are providing the most high value documents to the members that is organized and easy to access.

So I think we can have the portal up in

the short term and start, you know, start putting together that list of documents. You know, I think stemming out of that SSA is going to be important as a starting point.

And we can work with you on the types of documents that you're interested in, and maybe SHINE might have a comment on this as well. But I think, you know, the desire is to make sure that we're being responsive the most safety significant concerns that the ACRS members have, and not necessarily just overwhelming you with all of the hundreds of thousands of documents that SHINE has that are non-docketed.

MEMBER REMPE: So I hear that you're going to try and get it to us soon. I understand that it may not be complete, but I know in later slides you grouped chapters and I'm not sure which grouping will come to us first.

But maybe a preliminary list of some of the supporting documents that you find most important could be provided in a list by, within the next couple of weeks or when?

MR. LYNCH: Sure. We can -- so following this meeting, I'll have a conversation with SHINE and let's see, within the next couple weeks maybe we can make a goal of, where are we at, prior to maybe that

week of November 16th.

So prior to Thanksgiving we could work on having that portal up and some initial documentation. And what can be helpful too is maybe after we get those initial documents, receive some feedback from the ACRS members on the types of documents.

I can work with SHINE on highlighting for each of the technical areas, maybe if there are certain supporting documents that may be of interest. Maybe there are certain documents related to seismic analysis or aircraft impact that would be interest.

But we can, I'll work with SHINE on identifying that.

MEMBER REMPE: A couple of weeks with the list and some preliminary set of documents would be awesome. Thank you.

CHAIRMAN BALLINGER: You know we need to, I'm sure we, you know, we need to work through Chris on this.

MR. BARTELME: And Steve, that's certainly something SHINE can support. We can get that ACRS specific reading groups quite quickly, and we'll get a line of document types. So we can pool them and make them available quickly.

MR. LYNCH: All right. So I am realizing

that we're starting to -- it is 12:40 so I'll speak a little bit more quickly through these next slides so that we are affording some time for closing comments from the members.

So where we're at here is we have established a 24-month review schedule to prepare the safety evaluation for the SHINE application. And that was established in April of this year.

So our goal is to complete our technical review and have a complete safety evaluation prepared by October of next year.

I talked through most of this so I'll go through these slides relatively quickly. The main difference is I wanted to highlight here between construction permit and operating license application reviews is, while the processes are similar, we are looking at a FSAR and all of the information as presented in there.

As more or less a fresh review of information the difference then is with the supplemental environmental impact statement, that is more of a delta review that only new or significantly different information is evaluated.

Per our processes, we are still going through the ACRS subcommittee and full committee. And

then one of the differences we have here for our hearings is there is no mandatory hearing for the issuance of the operating license. There was only a mandatory hearing of the construction permit stage.

There was a notice, an opportunity for petition to leave and intervene in the SHINE proceedings. There were no requests for a contested hearing for this application.

Now as for the review methodology, similar to the construction permit and for the operating license application review, we are using NUREG-1537 as augmented by interim staff guidance for aqueous homogenous reactors and production facilities.

We are also using other guidance including regulatory guides and industry standards to conduct our review. Now, what's important about this, and I'm sure as the members look at the SHINE final safety analysis report and the NRC staff's SVR, our approach to looking at SHINE's application of codes and standards is really tailored to the commitments that they make in the FSAR.

Recognizing that for the most part particular codes and standards were developed for specific technologies that SHINE is not, including certain full cycle codes for criticality analysis,

codes for nuclear power reactors, codes for even research reactors.

So recognizing that not all of these codes and standards may be applicable in their entirety to SHINE as we are conducting our review of the application. We are paying particular attention to the commitments SHINE makes to either using codes in full or in part, and making sure that there is sufficient justification for how they are using these codes.

So that is probably one of the significant pieces of this review in ensuring that SHINE's adherence to their commitments to codes and standards is also supporting their principal design criterion identified in the application.

For the review as we discussed, I think at the internal ACRS on October 22nd, the NRC staff had broken up the review into some different review areas.

There were certain portions of the review that we were able to move straight to preparation of request for additional information. And then then there were other areas, such as the I&C systems, the accident analysis, criticality safety, that required more in-depth coordination with SHINE.

And what one of the ways that we pride

leveraging communication between the NRC and SHINE was, and continues to be, the use of regulatory audits to further our understanding of technical gaps that have been identified by the NRC staff and resolve those to the extent practical of the regulatory audits so that we can then issue focused requests for additional information and reduce the need for follow-up RAIs.

When it comes the issuance of the construction permit, again, the findings that we basically made were making sure that we had enough preliminary information to feel confident that SHINE could go and construct their facility.

It did not authorize to have any material on site. And essentially safety questions resulting from the final design would be resolved with the submission of the FSAR.

Now when it comes to issuing the operating license, the things that we're going to be looking at is making sure that we've met all of our safety evaluation findings described in NUREG-1537, making sure that again, some of these commitments that SHINE had made as documented in appendix A to the construction permit safety evaluation report have been addressed or superseded and we have documentation of that to close out those items.

And then when it comes to the specific regulation that we're looking at in 10 C.F.R. 50.57 for the issuance of an operating license, what I'd like to highlight here that's of particular importance as the staff completes its safety evaluation report, one of the other key findings that needs to be made is that construction has been substantially completed.

And this is where the licensing review and construction and construction inspection all come together. So once the NRC staff has completed its safety evaluation report, there is still another piece where once SHINE has completed its construction of its facility to include at a minimum the installation of all safety related structure, systems, and components, there is a notification that they will make to region two, which is responsible for construction inspection.

And once that notification has been received, region two will complete and verify that their inspection activities are resolved and there will be a letter from the region two administrator to the director of the office of Nuclear Reactor Regulation.

And that is the inspection piece that leads into the ultimate issuance of the operating license. So I did want to highlight that there. So in addition to completing our review of the application there is

the inspection piece that is necessary for the issuance of the operating license.

When it comes to the technical areas of the review, this is essentially the chapters of NUREG-1537. I do note that there are some of these areas that are not applicable to SHINE either at this time or at all.

For example, looking at experimental facilities, that's more common in research reactors, not here for SHINE. Also SHINE is not converting from HEU to LEU since they will be an LEU facility. So chapter on uranium conversions is also not applicable.

So most of these topics were covered at the construction permit stage. However, there are some additional technical areas that were not presented in the construction permit stage and will be presented to the ACRS members for the first time.

Some of those that I in particular that I'll highlight include a final emergency plan, a physical security plan, discussions of operator licensing start up, and human factors.

The one thing that I will note, a caveat with human factors program, this is something that the NRC staff is actively engaged with SHINE in to determine the appropriateness of scope for human factors against

SHINE's design criteria.

We do have a regulatory audit on SHINE's human factors, engineering program scheduled for tomorrow where our goal coming out of that audit is to have a clear idea of the necessity and scope of the NRC staff's evaluation of the human factors program. And I expect following that we'll have a clear path forward on how that will be factored into the NRC staff's review.

Going forward, I do want to highlight so there's a number of audits that we've conducted that have been very productive and resulted in significant progress for this review related to instrumentation and control systems, electrical power systems, accident analysis and criticality safety, physical security, and then as a result of the I&C audit we had back in March, SHINE did submit a revised I&C chapter 7 as part of its response to RAIs in that area in August of this year.

And our staff is actively reviewing that updated I&C chapter and I expect in the coming months that we may have additional RAIs and may engage with SHINE in future regulatory audits.

In terms of path forward on the licensing review, I did mention that we do have RAIs that are

ready to be issued related to the accident analysis, criticality safety, and chemical safety programs. SHINE is also in the process of responding to previously issues RAIs on external hazards and citing. And SHINE has provided responses to other RAIs related to instrumentation and control systems, their material control and accounting program, as well as facility descriptions.

There are some other technical areas that we are looking to schedule audits likely in the December and January timeframe. We need to work with SHINE on specific dates for that and as well as NRC staff so that we can have successful engagement.

Included in these are technical specifications, operator licensing, fire protection, and continued engagement on I&C systems. So with these regulatory audits, in preparation for those, we will put together technical topics that may for the basis of future RAIs.

And coming out of these audits, the goal is to have requests for additional information ready for issuance to have resolved.

MEMBER BLEY: Hey, Steve?

MR. LYNCH: Yes.

MEMBER BLEY: I know there's going to be

discussion between you and Ron and maybe some others about the topics at our upcoming meetings, but the first one's coming in January. Which kind of things would you even be prepared to talk about at that point?

MR. LYNCH: So that's actually something I would like to talk about and need to do some internal planning on how that's going to look. Probably where we're at, some of the high level facility descriptions are probably where we're mostly at. But I can skip ahead to some of our proposals engaging with the ACRS.

One of the things that we have been considering as the NRC staff is whether in order to facilitate some of our discussions, if it makes sense to have some of our first discussions with the ACRS focused on those most safety significant items, including the accident analysis, crit safety, chem safety, how that relates to engineering safety features, radiation and protection, looking at external hazards, and grouping all of that together.

While we have some of that information available now, we are expecting to get additional information on SHINE hopefully closing out most of those areas by early December, which would put us in a position to have updated safety evaluation input likely in the January, February timeframe.

So I do want to talk about with Ron and Chris about what makes sense with some of these presentations. Because one thing, while we can start providing chapters, what I want to make sure is that when we're sitting in front of the members that recognizing some of the interconnectedness especially with some of the safety significant portions, that as questions come up we're able to fully respond to that with the full context of completed other areas of the review.

So that is something I do want to discuss. I've got a meeting I believe Friday morning with Chris and Ron to discuss that in more detail about how we want to proceed in grouping these chapters and what topics are best to start discussing.

I know there are some areas of particularly MC&A that are wrapped up and probably ready for discussion, doesn't make sense to talk about that ahead of some of the other areas. We can figure out what makes the most sense.

MEMBER BLEY: Thanks. I don't want to try to pin it down right now but I think you can talk with our guys and get that arranged.

Just off the top of my head, I'm thinking under accident analysis, criticality safety, and

chemical safety, getting an as early as possible look at the range of scenarios, if you will, that are being considered, or events that are being considered --

MR. LYNCH: Yes.

MEMBER BLEY: -- would be a big help because that could focus what comes later.

MR. LYNCH: Yes, absolutely. And I think as part of our commitment to start getting documents upload to an electronic reading room for the members, having access to that SHINE safety analysis is going to provide that full context of what were all of the initiating events and scenarios considered by SHINE that ultimately translated to the design basis accidents and the controls that you see for the facility.

And that we can have for the members in the next couple weeks.

MEMBER BLEY: That's great.

MR. LYNCH: So I think this really -- so, yes, I've got, so I think this does kind of conclude the main remarks I have. I have got, yes, I have these proposals of how we can group some of these chapters based on safety significance and similar cross-cutting areas between them that I think make sense to talk about.

As we prepare for these subcommittee

meetings I know there is a chart of looking at identifying within each of these chapters what are the most safety significant items we're focusing on and we can certainly work with SHINE and with the ACRS on aligning on what those areas are so that we can put together those focused presentations for the members.

In terms of going forward, I do want to make sure that we are getting information to the ACRS in a timely manner so that you're able to have sufficient time to review available materials the NRC staff generates, and also that SHINE has prepared either as docketed material or available in an electronic reading room.

To the extent that we need to coordinate with ACRS staff as well as members ahead of subcommittee meetings to make sure that we're aligned on the key focus areas, we are available for that and we look forward to the continued engagement with the ACRS.

And I think with that that concludes the presentation materials that I had.

CHAIRMAN BALLINGER: Thanks, Steve. Okay, we're a little bit, well, we're almost there. Questions from the members? I think we do have to go back and open the public line for public comment.

So while we're getting that line open, do

we have comments from the members?

Silence is golden, I guess. Is the public line open, Tom?

MALE PARTICIPANT: Public line is open for comment.

CHAIRMAN BALLINGER: Okay. Are there any folks out on the public line that would like to make a comment? Please identify yourself and make your comment.

Okay. I don't hear any comments. Okay, this pretty much ends it, ends today's session. I think the last couple of slides that Steve presented are, at least from my standpoint, the critical ones because we're having to hone in on the methodology, the path forward for review by the committee, and we anticipate that that will be established at the December P&P meeting.

So that's our milestone. So I would encourage members to provide feedback through Chris to me, or both of us, related to this presentation and anything else that you think is important for the discussion in December.

And that pretty much ends it. So if there are no other comments or questions from the members, thank you very much for, to the SHINE people as well,

for a great presentation, and for Steve and staff to do the same.

So I think we are five minutes late, but not so bad. So thank you very much and we are adjourned.

(Whereupon, the above-entitled matter went off the record at 1:00 p.m.)

SHINE Overview (Open Session)

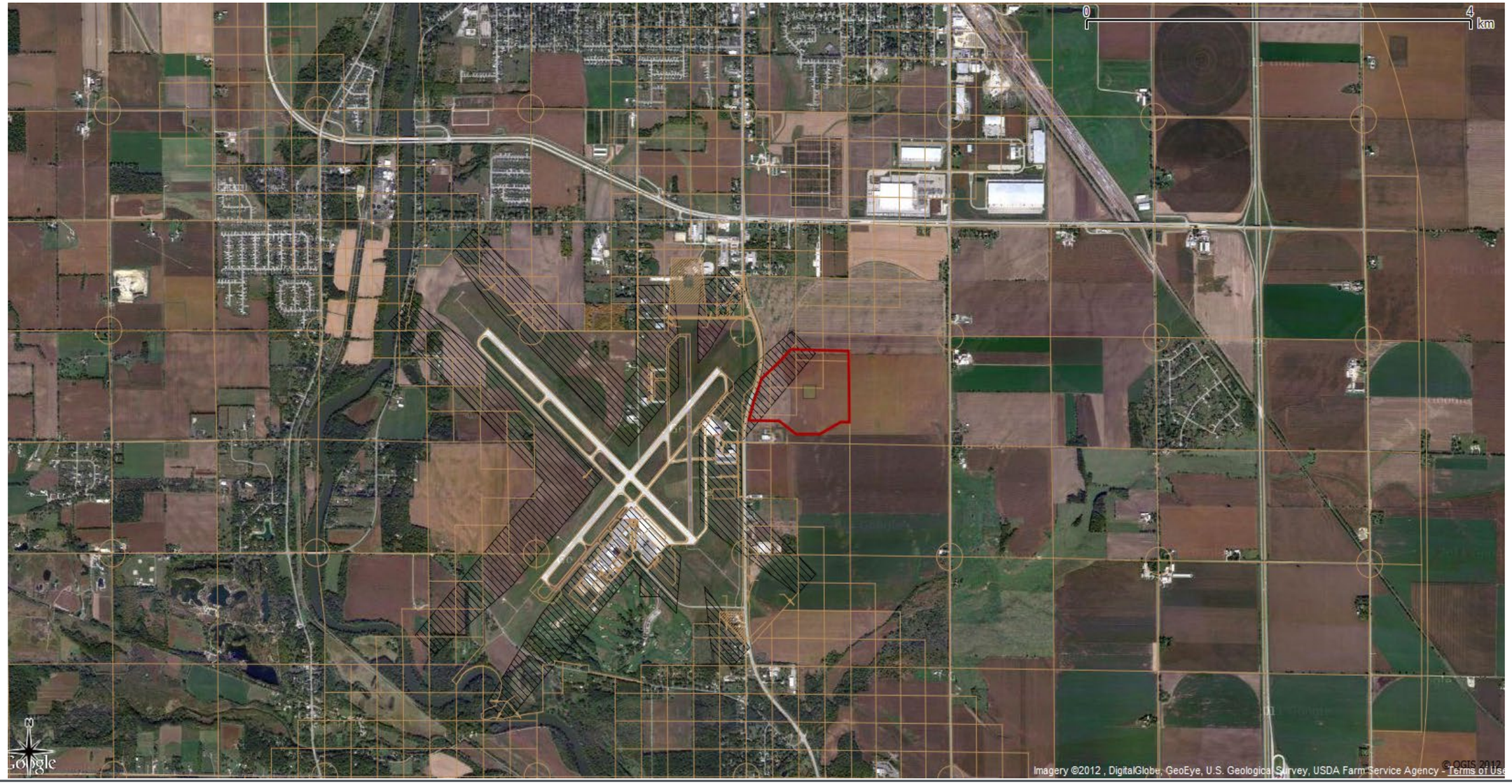
Tracy Radel, VP of Engineering

Health. Illuminated.™

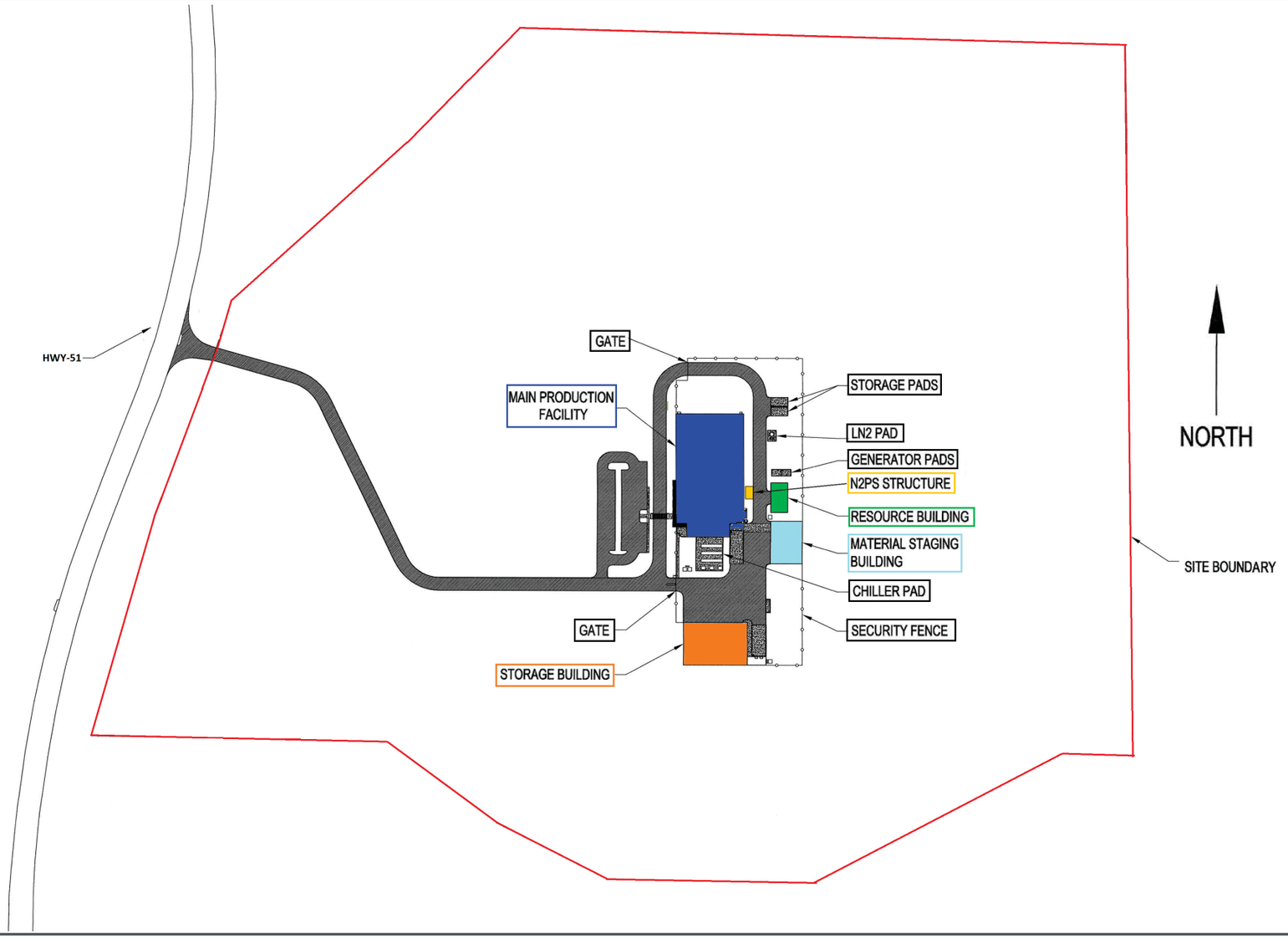
Outline (Open Session)

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

Located in Janesville, WI



Site Plan

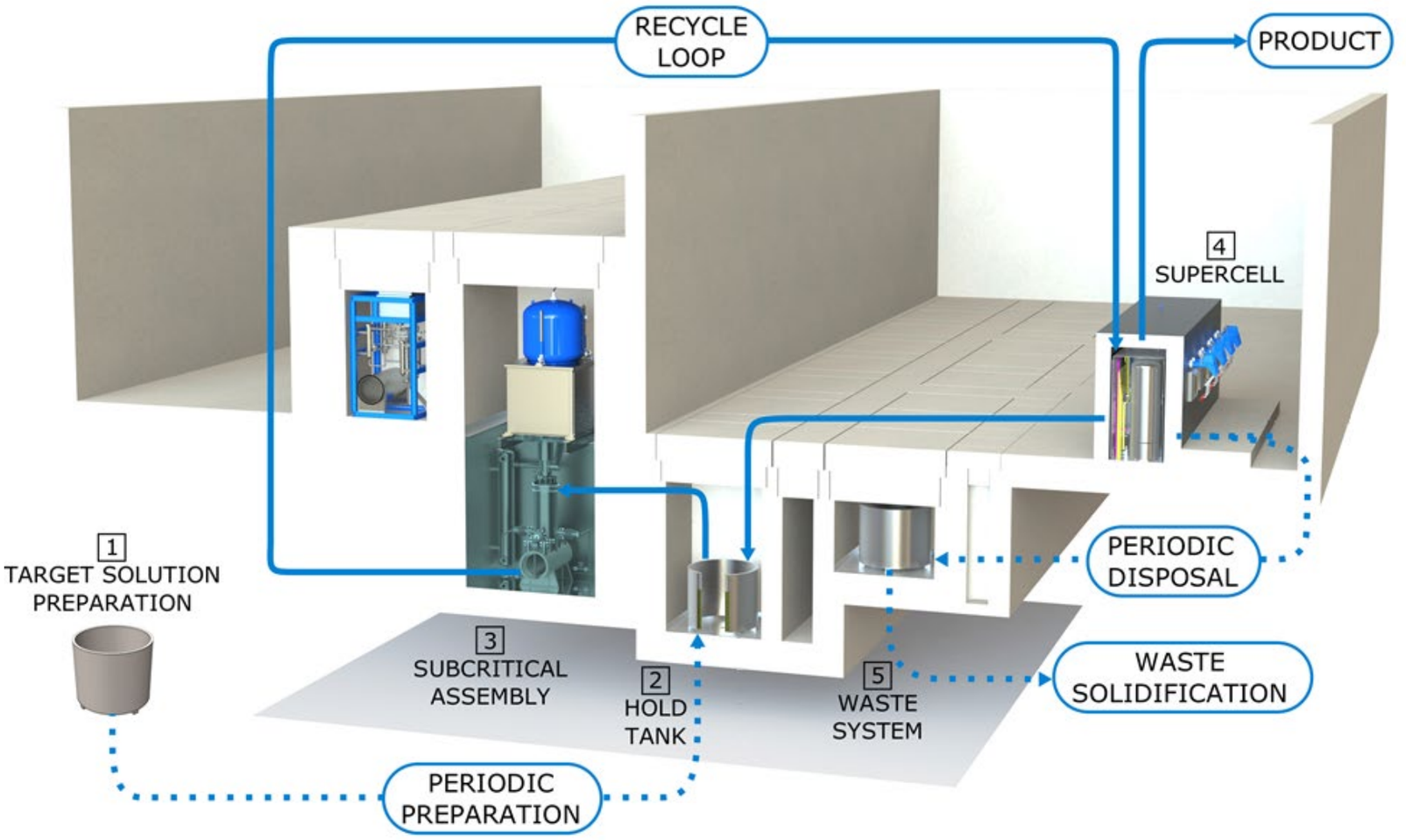

HWY-51
GATE
MAIN PRODUCTION FACILITY
STORAGE PADS
LN2 PAD
GENERATOR PADS
N2PS STRUCTURE
RESOURCE BUILDING
MATERIAL STAGING BUILDING
CHILLER PAD
SECURITY FENCE
GATE
STORAGE BUILDING
NORTH
SITE BOUNDARY

Site Rendering

Construction Status

Process Overview

1. Periodic solution preparation from LEU
2. Solution chemistry check and staging
3. Irradiation for 5.5 days
4. Extraction, purification, QC & packaging
5. Waste handling



Technological Approach

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

Safety Philosophy

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

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Advisory Committee on Reactor Safeguards
Non-Power Production or Utilization Facility Subcommittee

SHINE Medical Technologies, LLC Operating License Application Review

Steven Lynch, Senior Project Manager
Non-Power Production and Utilization Facility License Branch
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
November 2020

Supporting Domestic ^{99}Mo Production

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

Government Coordination and Legislation

- NRC staff coordinate other federal agencies, as well as local and state governments to support initial licensing application reviews
  - Department of Energy/National Nuclear Security Administration (NNSA)
  - Department of Homeland Security
- *American Medical Isotopes Production Act* provides for NRC and NNSA coordination on environmental reviews and the establishment of a uranium lease and takeback program
- *Nuclear Energy Innovation and Modernization Act* establishes three-year review period for non-power production or utilization facility initial licensing applications

Policy Work

- Non-Power Production or Utilization Facility License Renewal Final Rule
  - Final rule submitted to the Commission on June 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML18031A001)
  - Implements Commission direction to streamline the license renewal process by establishing a more efficient, effective and focused regulatory framework
  - Uses innovative and transformative approaches to address existing shortcomings in the current regulations for non-power licensees, including establishing accident dose criterion and clarifying definitions
- Definition of Utilization Facility Direct Final Rule
  - Final rule published in Federal Register on October 17, 2014 (79 FR 62329)
  - Added definition of utilization facility to include SHINE accelerator-driven subcritical operating assemblies

Regulated Radioisotope Production Processes

- Target manufacturing
  - Preparation of low enriched uranium (LEU) targets for irradiation
- Target irradiation
  - Nuclear reactors
  - Subcritical operating assemblies
  - Accelerators
- Target processing
  - Hot cell separation of ^{99}Mo from irradiated LEU targets
- Medical uses of byproduct material
  - Generators for extracting technetium-99m from ^{99}Mo

Similarities to Existing Facilities

- Safety considerations comparable non-power reactors:
  - Fission heat removal
  - Decay heat generation
  - Fission gas release
  - Fission product buildup
  - Accident scenarios
- …and fuel cycle facilities:
  - Target manufacturing
  - Radiation protection
  - Material processing
  - Criticality control
  - Chemical hazards

Responsibilities and Coordination

- The Division of Advanced Reactors and Non-Power Production and Utilization Facilities (DANU) is responsible, in part, for initial licensing activities associated with NPUFs licensed under 10 CFR Part 50.

- The following types of facilities may be licensed as commercial or research and development facilities under Sections 103 or 104 of the Atomic Energy Act, respectively:
  - Non-Power Reactors, including advanced reactor technologies
  - Subcritical Operating Assemblies
  - Production Facilities

- NRR relies on the expertise and support of other offices in the following technical areas to review medical radioisotope facility applications:
  - Emergency Planning
  - Physical Security
  - Environmental
  - Financial Qualifications
  - Material Control and Accounting
  - Accident Analysis
  - Chemical safety
  - Criticality Safety

Policy Work

- Non-Power Production or Utilization Facility License Renewal Final Rule
  - Final rule submitted to the Commission on June 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML18031A001)
  - Implements Commission direction to streamline the license renewal process by establishing a more efficient, effective and focused regulatory framework
  - Uses innovative and transformative approaches to address existing shortcomings in the current regulations for non-power licensees, including establishing accident dose criterion and clarifying definitions
- Definition of Utilization Facility Direct Final Rule
  - Final rule published in Federal Register on October 17, 2014 (79 FR 62329)
  - Added definition of utilization facility to include SHINE accelerator-driven subcritical operating assemblies

SHINE Medical Technologies Background

- NRC received two-part construction permit application
  - Environmental Report (March 26, 2013)
  - Preliminary Safety Analysis Report (May 31, 2013)
- SHINE proposes to produce ^{99}Mo from fission of low enriched uranium target solution in Irradiation Facility consisting of 8 irradiation units
- ^{99}Mo recovered through irradiated target solution processing in Radioisotope Production Facility consisting of 3 hot cells
- Construction permit issued on February 29, 2016
- Construction commenced in September 2019
- Site: Janesville, WI

Periodic Reports on Permit Conditions

- Section 3.D.(1) of SHINE construction permit requires the submission of periodic reports to verify certain design elements related to nuclear criticality safety and radiation protection
  - Criticality accident alarm system
  - Nuclear criticality safety evaluations
  - Design information demonstrating shielding and occupancy times consistent with as low as reasonably achievable practices and dose requirements
- These reports generally supported potential construction inspection activities prior to the submission of an operating license application
- NRC staff reviewing current information final safety analysis report, as supplemented.

Licensing Overview: SHINE Irradiation Facility

- Irradiation facility houses eight subcritical irradiation units, which are comparable in power level and safety considerations to existing non-power reactors licensed under 10 CFR Part 50

- However, due to subcriticality, irradiation units did not meet the existing definition of utilization facility in 10 CFR 50.2 and could not be licensed under 10 CFR Part 70

- To align licensing process with potential hazards, NRC issued direct final rule modifying 10 CFR definition of utilization facility to include SHINE irradiation units
  - Published October 17, 2014
  - Effective December 31, 2014

Licensing Overview: SHINE Radioisotope Production Facility

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

SHINE General Licensing Approach

- SHINE requested single operating license under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities”
  - Irradiation units licensed as *utilization facilities*
  - Hot cells licensed as *production facility*
- Special nuclear material will be licensed under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material”
- Source material to be licensed under 10 CFR Part 40, “Domestic Licensing of Source Material”

SHINE Operating License Application

- SHINE submitted operating license application on July 17, 2019

- Operating license application accepted for review on October 8, 2019, noting the following areas that would require focused engagement with the NRC staff (ADAMS Accession No. ML19276D409):
  - Instrumentation and Control Systems
  - Accident Analysis and Methodologies

- Following public meetings and regulatory audits on these technical review areas, a schedule of 24 months was established in April 2020 (ADAMS Accession No. ML20114E315)

10 CFR Part 50 Licensing Process

- Similar review process for construction permit and operating license applications:
  - Acceptance and docketing review
  - Parallel safety and environmental reviews
    - Construction permit: preparation of safety evaluation report (SER) and environmental impact statement (EIS) (or environmental assessment)
    - Operating license: preparation of SER and supplemental EIS (or environmental assessment)
  - Request(s) for additional information, as needed
  - Advisory Committee on Reactor Safeguards (ACRS) review
  - Hearing(s)
    - Construction permit and operating license: potential for contested hearing(s)
    - Construction permit: mandatory hearing on sufficiency of staff safety and environmental reviews
  - Decision to grant or deny permit or license

NRC Safety Review Methodology

- Safety reviews for construction permit and operating license applications conducted in accordance with Commission's regulations
- The level of detail needed in a construction permit application and NRC staff's SER different than for combined operating license or operating license
  - The PSAR includes preliminary design of the facility, while the FSAR includes final design of the facility, as well as plans and programs not provided in PSAR
- Staff's review tailored to unique and novel technology described in construction permit application using appropriate regulatory guidance
  - NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors"
  - Interim Staff Guidance Augmenting NUREG-1537
  - Other guidance (e.g., regulatory guides and industry standards) and engineering judgment used, as appropriate

Review Approach

In order to focus resources and efficiently complete the review of the SHINE operating license application, the staff is applying a tiered review strategy. Technical areas within the application are assigned review levels corresponding to scheduled milestones based on the complexity of the subject matter, availability of information, and maturity of design.

The review levels are defined as:

- **Level 1**: No clarification questions needed, information readily available, direct preparation of requests for additional information (RAIs)
- **Level 2**: Initial clarification questions needed, reference documents requested, and public meetings needed prior to developing RAIs
- **Level 3**: Fundamental scoping questions, clarification questions, public meetings, audits, and application supplements needed prior to developing RAIs

- Review Strategies:
  - Use of focused review groups
  - Leverage scaled review methodologies
  - Exchange of technical and licensing expertise
  - Establish clear responsibilities to ensure responsiveness and timeliness

Basis for Issuing Construction Permit

- The following findings must be made to issue a construction permit, based on 10 CFR 50.35:
  - Facility has been described, including the principal architectural and engineering criteria for the design
  - Further technical or design information may be reasonably left for later consideration in the FSAR
  - Safety features or components requiring research and development have been identified
  - Safety questions will be resolved prior to the completion of construction and the proposed facility can be constructed without undue risk to the health and safety of the public
- Staff's conclusions also based on the considerations in 10 CFR 50.40 and 50.50

Basis for Issuing Operating License

- The review of the operating license application is not a delta review of the construction permit application
- NRC staff consider commitments made by the applicant in Appendix A to the construction permit Safety Evaluation Report in preparing requests for additional information
- The following findings must be made to issue a construction permit, based on 10 CFR 50.57:
  - Construction has been substantially completed
  - Facility will operate in conformity with application and regulations
  - Reasonable assurance that operation will not endanger public health and safety
  - Applicant technically and financially qualified
  - Provisions of 10 CFR Part 140 satisfied
  - Issuance of license will not be inimical to common defense and security

NUREG-1537 Review Areas

1. The Facility/Introduction
2. Site Characteristics
3. Design of Structures, Systems, and Components
4. Facility Description
5. Coolant Systems
6. Engineered Safety Features
7. Instrumentation and Control
8. Electrical Power Systems
9. Auxiliary Systems
10. Experimental Facilities*
11. Radiation Protection and Waste Management
12. Conduct of Operations
    - Emergency Planning
    - Physical Security
    - Operator Licensing
    - Startup Plan
    - Human Factors
    - Quality Assurance
13. Accident Analysis
14. Technical Specifications
15. Financial Qualifications
16. Other License Considerations*
17. Decommissioning*
18. Uranium Conversions*
19. Environmental Review

*Not applicable to the SHINE operating license application

Review Status

Recent Milestones Achieved:

- Conducted instrumentation and control audit (March 2020)
- Conducted electrical power systems audit (May 2020)
- Conducted accident analysis and criticality safety audit (August 2020)
- Conducted security audit (September 2020)
- Received revised Instrumentation and Control Chapter 7 (August 2020)

Upcoming Milestones:

- Conducting human factors and startup plan audit (November 2020)
- Conducting technical specification audit (TBD)
- Conducting operating licensing audit (TBD)
- Conducting fire protection audit (TBD)
- Conducting additional instrumentation and control audit (TBD)

Review Schedule

In April 2020, staff established shortened 24-month review schedule and resource estimate of 22,000 hours based on availability of additional information on SHINE's accident analysis and instrumentation and control (I&C) systems

Milestone	Est. Completion Date	Actual Completion Date	Status
Acceptance and Docketing of Application	October 2019	October 2019	Complete
ACRS Subcommittee Planning Meeting	October 22, 2020	TBD	Pending
ACRS Subcommittee Meeting	November 4, 2020	TBD	Pending
Publication of Draft EIS Supplement	January 2021	TBD	Pending
Publication of Final EIS Supplement	August 2021	TBD	Pending
Draft Safety Evaluation Complete	July 2021	TBD	Pending
ACRS Full Committee Meeting	September 2021	TBD	Pending
Final Safety Evaluation Report Complete	September 2021	TBD	Pending
Final Determination on Issuance of Operating License	October 2021	TBD	Pending

Project Risks

Technical Risks

Risk	Risk Level	Mitigation
SHINE development of I&C systems delays due to revision of FSAR in August 2020	Moderate	Engagement with SHINE to align on what information is most safety-significant

Schedule Risks

Risk	Risk Level	Mitigation
Potential design changes, including development of I&C systems	Moderate	Outside of NRC staff control
Revision of physical security plan	Moderate	Staff working with SHINE on receiving revision to avoid unnecessary RAIs
Staff turnover following closeout of review areas ahead of overall project completion	Moderate	1. Closeout ACRS actions within 90 days of subcommittee meetings 2. Identify and resolve legal questions early
SHINE timeliness in responding to RAIs	Moderate	Staff coordination with SHINE to ensure draft RAIs are well-understood and reasonable response timeframes are established
SHINE completion of construction	Moderate	Outside of NRC staff control

Cost Risks

- *None at this time*

Policy Risks

- *None at this time*

ACRS Subcommittee Engagement

- Present on technical topics based on safety-significance and relation to other topics
- Present on technical topics only after NRC staff has resolved all open items with licensee
- Staff propose three subcommittee meetings, organized by the safety-significance of technical areas, covering all chapters of the application
    - Prior to scheduled subcommittee meetings, staff will identify most safety significant areas within each topic that merit focused discussion
    - For areas that don't require focused technical discussion, staff and applicant will be prepared to answer questions, but may not have prepared materials

ACRS Subcommittee Engagement (Continued)

- Subcommittee Topic Grouping 1:
  - Facility Description (Chapters 1, 4)
  - Accident Analysis (Chapter 13)
  - Criticality Safety (Chapter 6, 13)
  - Chemical Safety (Chapter 4, 13)
  - Engineered Safety Features (Chapter 6)
  - Site Characteristics and External Hazards (Chapters 2, 3)
  - Radiation Protection and Waste Management (Chapter 11)

- Subcommittee Topic Grouping 2:
  - Instrumentation and Control Systems (Chapter 7)
  - Electrical Power Systems (Chapter 8)
  - Coolant Systems (Chapter 5)
  - Conduct of Operations (Chapter 12)
    - Emergency Planning
    - Physical Security
    - Operator Licensing
    - Startup Plan
    - Human Factors
    - Quality Assurance

- Subcommittee Topic Grouping 3:
  - Technical Specifications (Chapter 14)
  - Follow-up items

Success Strategies

- Early and frequent engagement with SHINE
  - Leverage use of electronic reading room, audits, public meetings, and clarification calls to improve understanding of application
- Leverage Technology
  - Use of electronic reading rooms, virtual meetings
- Communication at all levels
  - Communicate and align on key messages and review approaches across offices and at all organizational levels
  - Communicate review status and key milestones with Advisory Committee on Reactor Safeguards