

# **Corrected Transcript**

## **Official Transcript of Proceedings**

### **NUCLEAR REGULATORY COMMISSION**

Title: SHINE Medical Technologies, LLC  
Medical Isotope Production Facility  
Operating License Application  
Public Scoping Meeting

Docket Number: (n/a)

Location: Janesville, Wisconsin

Date: Thursday, December 12, 2019

Work Order No.: NRC-0715

Pages 1-25

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UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

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PUBLIC MEETING TO DISCUSS THE ENVIRONMENTAL REVIEW  
AND SCOPING PROCESS FOR THE SHINE MEDICAL  
TECHNOLOGIES, LLC MEDICAL ISOTOPE PRODUCTION  
FACILITY OPERATING LICENSE APPLICATION

+ + + + +

THURSDAY

DECEMBER 12, 2019

+ + + + +

The Public Meeting was convened in The  
Celtic House at Glen Erin Golf Club, 1417 West  
Airport Road, Janesville, Wisconsin at 6:00 p.m.,  
Lance Rakovan, Facilitator, presiding.

PRESENT:

LANCE RAKOVAN, Facilitator

STEVEN LYNCH, Safety Project Manager

JENNIFER DAVIS, Environmental Project Manager

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

MR. RAKOVAN: Hi, so, let me just start by saying that it is so unusual that everybody just kind of gets into their seats right as the meeting is about to begin, and it's quiet, and this is fantastic. I can't wait to come back to Wisconsin.

Good evening, everyone. My name is Lance Rakovan. I am a liaison with the U.S. Nuclear Regulatory Commission, and I'm going to be facilitating tonight's meeting. In that regard, we're hoping to make this meeting as educational and informative for you, and ~~hope~~ to collect a lot of comments as well and we hope that you'll help us with that.

The purpose of this meeting is to gather information, to prepare a supplement to NUREG--2183, talk about that in a second, as part of the review of the SHINE Operating License Application submitted to the NRC. Now, NUREG--2183 is the final environmental impact statement developed for the SHINE construction permit, and NRC is seeking public input on the proposed action and has scheduled this public meeting to listen to your comments.

A term that you're going to hear a lot tonight is scoping. It means determining the scope

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of the environmental review, in this case for the SHINE facility. Today's meeting is just one way that you can participate in that process, and you'll be hearing more about that soon.

Tonight's meeting will essentially have two parts. First, we'll hear some presentations from NRC staff on both the safety and environmental review processes, information we think is important for you to understand. There's copies of the presentation over on the table over there. If you didn't have a chance to pick up one, I'll run a few copies around; just give ~~me~~you a heads up and I can bring one to you.

We're going to try to keep these presentations short so we can get to the real reason that we're here, the second part of the meeting, which is to listen to you. There were yellow cards on the table that we asked you to fill out if you wanted to speak today. If you didn't fill one out, that's fine. This just helps us organize and keep track of our speakers and make sure that we get your name properly on the transcript.

We are transcribing today's meeting, and again that's to make sure that we understand and fully get your comments that are made during the meeting.

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We're not trying to paraphrase them or, you know, trying to play catch-up with just notes that we've taken. So, we will have a firm transcript.

You can help us get a good transcript of the meeting ~~byte~~ make sure that we keep noise, sound level, side conversations, et cetera, quiet. If you need to have a side conversation, please step out to the back. If you could take a moment to silence your electronic devices or turn them off, that will help avoid distractions as well.

We are also doing this meeting by Skype. So, if anyone is on Skype and you're not muted, please keep your phone muted, or keep your end of the Skype muted so we don't hear dogs barking, those kinds of things that can disrupt a meeting.

There were also some other items on the table over there that provide information on NRC in general, and also specific to SHINE. So, again, if you didn't have a chance to pick those items up when you came in, by all means please stop by the table on your way out. Again, I'll run the slides by in a moment.

There's also a public meeting feedback form, if you have a moment to fill that out, or you can also do it electronically online just to let us

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know what you thought of tonight's meeting. If you have any suggestions on how we could be more productive with these types of meetings in the future, by all means, please either take a copy and drop it in the mail, or go online and fill that out for us.

Restrooms are out ~~and into~~ the right ~~17~~ down the hallway to the right. Exits are kind of visible really in three out of four directions, so if anything happens, just don't head that way and you should find an exit fairly quick.

I wanted to take a moment to introduce our speakers. Tonight, we have Steve Lynch. He is the lead for the safety review of the proposed SHINE facility. Steve is a project manager in the Non-Power Production and Utilization Facility Licensing Branch. He coordinates the NRC's licensing of facilities intending to produce molybdenum-99, and supports preparations for anticipated applications for advanced reactor technologies.

We also have Jennifer Davis who is the lead for the environmental review for the proposed SHINE facility. She is a senior project manager in the NRC's Office of Nuclear Material Safety and Safeguards, and has 17 years of environmental project management experience involving various licensing

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projects.

We do have other NRC staff available tonight if you have questions on other aspects of the NRC, what we do, and also specific to the SHINE facility. So, if you have questions after the meeting and you're looking for someone specific to talk to, just grab one of us NRC folks, and we'll try to either get the right person to talk to you here, or get your information and we can get back to you at a later date.

So, with that, I'd like to turn it over to the speakers. Essentially, like I said, tonight we'll have our presentations. After we have the presentations, I'll open the floor up to clarifying questions specific to the presentations. If you have questions that are outside of our safety and environmental review processes, we'll ask that you either have that again off to the side or at a later date, and then we'll go ahead and open it up and we'll invite people to come up here to the podium to provide their scoping comments. If you do have questions, again please ~~let's~~ let the speakers get through their presentations, and we'll go ahead and open it up for questions when they're done.

So, with that, I'm going to turn things

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over to Steve to give the presentation on the safety review process.

MR. LYNCH: Right, thank you, Lance. All right, so to get things started before we get into the specifics on the SHINE project, I want to provide a little bit of background information on the actual purpose of the facility once it is operational, should the NRC staff complete its review and determine that an operating license should be issued.

The facility would produce molybdenum-99 which decays into another radioisotope, technetium-99 metastable which is used in medical procedures. One of the most common procedures that it's used for is in cardiac perfusion testing or heart stress tests to understand the function of your heart. 50,000 procedures using moly-99 are performed each day.

Until recently, there had been no domestically produced supply. There are some limited commercial supply available today from NorthStar Radioisotopes and their ~~Radio~~Genix generator. But the last operating facility producing wide-scale commercial molybdenum-99 in the United States was from a company called Cientichem back in the late 1980's.

Currently, the U.S. is mostly reliant on

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international reactors to receive its supply of this medical radioisotope. Facilities are located around the world, in Australia, South Africa, the Netherlands among others. But this dependence on these facilities that are far away has jeopardized supply. Some of these reactors have aged and have had to have extended shutdowns for repairs, which has jeopardized supply and the availability of medical treatments to U.S. patients.

So, how does the NRC fit in-to the review of the SHINE application and helping to establish a reliable supply of molybdenum-99 in the U.S.? So, we are an independent regulator that looks at a variety of different processes that are involved in the actual production of molybdenum-99. We'll consider applications from facilities that will perform a number of actions such as manufacturing targets that would ultimately be irradiated and/or processed to get the actual isotope. These targets may be in the form of uranium that the molybdenum-99 would be a fission product of, or some non-radioactive molybdenum targets could then be irradiated as well to produce the isotope. All of these reviews by the NRC do support U.S. government goals of supporting the establishment of a domestically available and

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reliable supply of this isotope for U.S. patient care.

As far as what the NRC looks at, we're guided by our sets of regulations in Title 10 of the Code of Federal Regulations, and specifically with the SHINE application, we have a Part 50 that looks at utilization facilities and production facilities that again are used in this case for irradiating material and processing it to get the molybdenum-99. But above that, we do have some higher statutes of law that inform the development of our regulations. We have the Atomic Energy Act of 1954 which created the Atomic Energy Commission and the regulations that followed for reactor technologies and material, -and the responsibilities of the federal government for licensing and overseeing the use of this material.

A couple of decades later, the Energy Reorganization Act formally created the NRC as an independent regulator. With the NRC, we do have a couple of high level objectives as our agency or guiding principles for looking at applications and making our findings of reasonable assurance that facilities could be operated safely. We want to make sure that the public health and safety is protected. We are promoting the common defense and security, and also protecting the environment.

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Now, getting a little bit into high level description of the SHINE technology and what they're actually proposing, so SHINE has proposed to construct and operate eight irradiation units that are being licensed as utilization facilities. So, essentially, what these will look like will be large pots of liquid uranium that can be irradiated with neutrons from an accelerator source that then would generate fission products including the molybdenum-99 that SHINE would then recover in a series of hot cells where they could chemically process the solution to extract the molybdenum and then be able to have that transferred off site to be converted into medical radioisotope technetium.

As far as where this facility is located, so here we have some specifics on the slide of it being four miles south of Janesville. A little more specifically, it's actually just across the road here, and you can see the cranes on site where SHINE has just started pouring concrete on that, just on Highway 51 there.

As far as some of the NRC's involvement over the years, so we have reviewed and approved the construction permit. SHINE submitted that initial construction permit application to us back in 2013.

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There was a two-part review that we conducted back then, looking at the safety and environmental aspects associated with the facility that resulted in the preparation of two different documents: one, a safety evaluation report documenting the NRC staff's findings on whether or not we had confidence based on the preliminary design that the facility could be constructed and operated safely; and an environmental impact statement looking at the impact of the facility on the surrounding environment. Following our review of that application, we did issue a construction permit to SHINE back in February of 2016. A couple of months ago in September, SHINE actually began construction.

Now, we've moved into a new phase of the review. Back in July of this year, SHINE submitted an operating license application. The operating license application updates information that was initially provided in the construction permit application. It provides the NRC staff with a final design of the facility.

With this new information, we will conduct a review and prepare two documents again. We prepared previously a preliminary safety analysis report; now we will have a final safety analysis

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report that will have updated conclusions that have considered the final design information provided by SHINE and would support the NRC staff in making a determination whether or not an operating license should be issued. There will also be an update to the environmental impact statement prepared by the NRC staff looking at any new information that has been made available since the preparation of the original environmental impact statement. Both of these documents will be based on information provided by SHINE in its application, in its final safety analysis report, and the supplement to its environmental report~~s~~.

The application was officially accepted by the NRC for review back in October of this year, and the staff is currently engaged in its detailed technical review.

So, what do these processes look like when we're evaluating SHINE's application? So, as I just mentioned, we accepted the SHINE operating license application back in October. That kind of corresponds to that first bullet on this slide here, that initial NRC staff review. Once we find that the application is acceptable and begin our detailed review of the application, we may come up with

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questions for the applicant to better understand the information that was provided and make sure that we have all of the necessary information to make our safety findings.

Once we have had all of our questions answered, the NRC staff then proceeds to prepare its documentation of its review and its safety evaluation report and environmental impact statement. Once these documents are prepared, there is another body within the NRC, the Advisory Committee on Reactor Safeguards, that performs an independent assessment of the NRC staff safety review and the application prepared by SHINE, and makes a recommendation of whether or not the license should be issued. That recommendation is provided to the NRC's ~~e~~Commission.

There's also, as part of the process, — an opportunity for those with standing to file a petition for an opportunity for leave to intervene and participate in a contested hearing on the proceedings. If that is granted, that hearing would be held as part of the NRC staff's review as well. Ultimately, after all of the steps have been completed, a decision will be made whether or not to grant or deny the license.

Now, on this slide here, we just have a

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visual representation of what that process I just had talked about looks like. After deciding to accept the application, there are the two main portions of the review, the safety and the environmental review. Tonight, after I talk about this big picture process, we'll mostly focus on getting more information from Jenny on the environmental review aspect of this and describing some of the steps of that process. But with the input from the safety review and the environmental review, the potential hearing, and the review by the ACRS, all feed in as inputs into the staff's decision of whether or not to issue the license to SHINE.

Now, before I turn it over to Jenny, I'll give a little bit of insight into what are the considerations that the NRC staff has as we perform our technical review as guided by the Atomic Energy Act and our regulations. So, in addition to some of those documents, we do have some internal staff guidance documents that have been developed specific to the technologies that SHINE has proposed. The documents that we most rely on to conduct our safety review are NUREG-1537, which provides a standard review plan, and a format and content guide for non-power reactors, as supplemented by some interim staff

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guidance for this document which provides additional information for aqueous facilities that are similar to SHINE's proposed irradiation units and radioisotope production facilities that are used for processing of special nuclear material. In addition to these main guidance documents, staff may also use their engineering judgment to reach appropriate safety conclusions.

With that, I will turn the presentation over to Jenny to talk about the staff's environmental review. Thank you.

MS. DAVIS: Thank you, Steve. Good evening, everyone. First off, I want to thank everybody for coming out tonight. It's a very busy time of year and we do appreciate your time.

My name is Jennifer Davis. I'm the environmental project manager for the operating license review, and I'm going to be providing you a brief overview of our environmental review process.

The NRC's review will be performed in accordance with the National Environmental Policy Act, commonly referred to as NEPA. NEPA requires federal agencies to follow a systematic approach in evaluating potential environmental impacts and to assess alternatives to those actions. The NEPA

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process also allows the public to participate within the environmental review. The NRC's environmental protection regulations implementing NEPA are located at 10 CFR Part 51. Next slide please.

The NRC issued NUREG--2183, the final environmental impact statement, or EIS as we're going to call it, for the construction permit in October of 2015. When an EIS has been prepared for a construction permit, NRC regulations require the preparation of a supplement to that EIS for the issuance of the operating license. This supplement will update the prior environmental review and will cover matters that differ or that reflects significant new information from that discussed in the prior ~~environmental~~-EIS.

This slide presents a high level overview of our environmental review process. The environmental review begins with the issuance of a notice of intent to prepare a final supplement and to conduct scoping. The notice of intent for the SHINE review was issued on November 27th, 2019.

The next box is scoping ~~which is~~ a process by which the NRC staff identifies specific impacts and significant issues to be considered in the preparation of the supplement. An important part

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of the scoping process ~~involves~~ public involvement. Information that we gather from you today and within the next coming weeks will be considered as we develop the supplement.

Following the scoping process, the NRC staff will be preparing the draft supplement, and we will be issuing that for public comment. This will also be another opportunity for public participation in the environmental review, and we will hold a public meeting on the draft supplement itself. Comments received on the draft will be considered as we develop the final supplement. Once issued, the final supplement will help inform the decision on whether or not to issue the operating license to the SHINE facility. Next slide please.

So, to briefly recap, the supplement is going to update the prior environmental review performed for the construction permit and describe matters that differ or that represent significant new information from what was discussed in NUREG--2183, such as:

- ! Changes to the facility design that could potentially affect the environment;
- ! Has the building footprint changed? What about the excavation depth, the ~~staeck~~ height?

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- ! Are there changes to facility operation that could affect the ~~new~~-environment?
- ! Is there a change in the number of workers?
- ! Are there new or revised production activities that could change air emissions or dose exposures?
- ! Have there been changes to the natural or physical environment?
- ! Are there new activities or facilities in the surrounding area?
- ! Are there changes in the regulatory environment? For example, are any new permits required?

These are among many things that we would be assessing during this time.

Public comments are an important part of our environmental review process, and this slide illustrates how we collect and utilize your comments. We respond to every comment that we receive as part of the environmental review. All comments received during the scoping period will be used to determine the scope of the supplement and will be documented in a scoping summary report. Similarly, after consideration of public comments received on the draft supplement, the final supplement will

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incorporate appropriate changes.

The results of the public involvement will be captured in an appendix to the supplement. So, the supplement is just one of the factors, as well as several others shown on the screen, that influence the Commission's decision whether or not they will issue a license. Next slide please.

There are multiple ways in which you can submit comments to the NRC. You can provide written comments at today's meeting by dropping them off at the registration table, or if you are brave, you can come up here and speak at the podium. Either way is fine. We have a court reporter here and he is here to help ~~with~~ us record all comments that we receive today.

You can also provide us with written comments via snail mail; that works, too, at the address that is listed on the slide. But we do ask that you specifically state that you're commenting on the SHINE operating license review. That helps our staff assign your comment to the appropriate licensinge docket. Next slide please.

You can also submit comments online using the federal rule—making website called regulations.gov. This is a federal government

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website that serves as a repository of information on the development of federal regulations and other related documents. This website allows for the public to search, review, and comment on regulatory issues that are important to you.

At the regulations.gov website, you will enter the NRC docket ID number that you see on this slide. It's NRC-2019-0173. This website will give you a list of associated federal registry notices with that docket. There will be an icon on the right-hand side that says Submit Comment. Should you wish to do it via this website, we do have a handout at our information table that kind of gives you step-by-step instructions on how to do that.

Please note that comments will not be edited to remove any identifying or contact information. So, do not include any information in your comments if you do not want it publicly disclosed. So, for example, you have a public comment that you're ~~issubmitting~~ to us and you want to receive a copy of the draft supplement in the file, ~~and~~ you may not want to include your home address. Feel free to e-mail me or Steve directly, and we will make sure that we add you to the distribution list.

Again, the deadline for submitting

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comments is going to be January 13th of 2020. Next slide.

A hard copy of SHINE's supplemental environmental report that they submitted to the NRC in October may be found at the Hedberg Public Library. Additionally, the draft supplement will be made available at this library once it is published for comment. These documents, including the publicly available operating license application, are available on the NRC's website at the web address shown on the slide.

The NRC has an official record-keeping system called Agencywide Documents Access and Management System or, as we simply call it, ADAMS, through which the NRC provides access to various collections of publicly available information. The ADAMS number that you see at the bottom of the slide will take you to SHINE's supplemental environmental report. Next slide.

This slide contains the contact information for both Steve and myself. We are the primary points of contact for the SHINE review. As Steve mentioned earlier, he is the safety project manager and I am the environmental project manager. So, should you have any questions in the future,

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please don't hesitate to reach out to us. That concludes my remarks.

MR. RAKOVAN: Thank you, Steve and Jen. At this point, we'd like to open the floor up if anybody has any clarifying questions specific to the safety or environmental reviews. If you do, just raise your hand. I've got a wireless microphone that I can bring to you. Again, if you have questions that are kind of outside of the scope of what Steve and Jen talked about, by all means, you know, grab us after the meeting, during the meeting, something like that, and we'll try to find either the right person to do it or to take care of your question if they're here, or we can get your information and try to have someone get back to you, because we don't want to just take guesses. We want to make sure we have you talking to the right person.

So, any questions for Steve or Jen on the safety or environmental review processes for the proposed facility? Okay, this is certainly not a speak-now-or-forever-hold-your-piece kind of thing, so I just want to make sure that you guys are aware of that.

Okay, so let's go ahead and move on to the scoping part of the meeting if you will, ~~or~~ we

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can listen to any scoping comments that you have. Again, we ask if you wanted to have the podium, that you fill out one of the yellow cards so we can make sure that we get your name right on the transcript. If you could, introduce yourself, even though I'm hopefully going to call your name and not slaughter ~~it~~you. We do only have one card at this point. I do have additional cards, so again if you decide that you'd like to speak, ~~raise~~give me your hands up and I'll bring you a card and you can fill it out and we'll get you up here.

The individual's name I have is Richard Krutzik. Sir, if you could please come take the podium?

MR. KRUTZIK: Hi, good evening. Richard Krutzik, I am from Elk Horn, Wisconsin. I came tonight to, I'll say offer some support for I think the importance of what's going on here. I'm a big believer in medical imaging. The fact that we don't have really a reliable domestic source in molybdenum-99 I think is a concern.

I just started my retirement. I was telling a couple of folks here I'm just going into retirement here. As we get older, the issues that come up on the health issues become more and more

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important.

When I was a kid, people would talk about doing exploratory surgery. You couldn't see inside the body; they had to open you up and have a look inside. That's all changed with the advent of nuclear medicine, radioactive isotopes.

I know the impact, or the question for Jenny is the environmental and safety. I think our NRC has done a very good job. I looked at the safety record of our nuclear industry, both from the reactor side and also for the nuclear medicine. They've done an excellent job of keeping the public safe here. I'm sure that she'll do a thorough review. I think we all want to be safe.

I also commend the folks for SHINE. I've had a chance to meet a few of those folks. I think they'll do a great job of meeting all the expectations that are laid out in their operating guideline and even may exceed those.

So, I'm just here to say I'd really like to see the establishment of that facility in Janesville. I think it does a lot for the area, and we welcome their presence. Thank you.

MR. RAKOVAN: Thank you, sir. Any other members of the public who would like some time at the

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microphone or have a question that you'd like to ask of Jen or Steve at this point? I'm not pausing for dramatic effect. I just want to make sure in case anybody is, you know.

Jen, did you want to come close the meeting or would you like me to close?

MR. LYNCH: First, anybody online who has a question?

MS. DAVIS: That's true, yes. Anyone online have any questions? Let me see if we can get them up.

Anyone online have any questions? Let's see, it looks like there's a comment. Okay, let's see. Unfortunately, it doesn't look like it. It was mainly questions on accessing the slides.

MR. RAKOVAN: Okay.

MS. DAVIS: Okay, we'll see.

MR. RAKOVAN: Again, you know, if you would like to stick around after the meeting, we do have several NRC staff here. You can look for the folks that have the name tags on. If they don't know the answer to any questions that you have, again we can hopefully connect you with the right people who do. Okay?

All right, well, thank you all for

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venturing out this evening. Hopefully we were able to educate you at least a little bit on the processes. Please be safe out there. Thank you.

(Whereupon, at 6:33 p.m., the above-mentioned public hearing was concluded.)

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